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13. ABSTRACT (Maximum 200 words) This objective of this project was to verify by direct measurement the filtration efficiency of the gas mask C2A1 canister in light of new bioaerosol threats. HEPA filters are routinely tested using an oil aerosol at the most penetrating particle diameter at 0.3um to verify that the efficiency is at least 99.97%. The program addressed two questions: 1. What is the filtration efficiency of the C2A1 canister under use conditions for the particle size range of potential biological threats in the 1 to 5 um size range; and 2. What would be the likely dose under conditions of extended use in highly biologically contaminated areas? Test procedures for quantifying HEPA canister efficiencies were developed using <i>Bacillus atrophaeus</i> (formerly <i>Bacillus globigii</i> or BG) spores and a polydisperse 0.3 – 10 µm non-biological aerosol. The procedure includes tests with non-biological aerosol to verify the bioaerosol results and allow application to a wider range of particle diameters. The fundamental test methodology is applicable to a wide range of filter configurations.				
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# **Validation of Respirator Filter Efficacy**

## **FINAL REPORT**

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## Validation of Respirator Filter Efficacy Final Report

### Executive Summary

- This program addressed the following question: Do the respirator canisters used by US military personnel (specifically the C2A1, R57B, and CP3N) provide sufficient protection in light of today's chemical and biological aerosol threats? Particles in the 1-5  $\mu\text{m}$  size range were of special interest because biological aerosols are often found in this range and because particles in this range are respirable.
- The C2A1 canister is manufactured to be a minimum of 99.990% efficient for 0.3  $\mu\text{m}$  diameter particles. Likewise, non-DOD approved canisters are tested by NIOSH to be a minimum of 99.97% efficient for 0.1 – 0.3  $\mu\text{m}$  particles. These standard measurements are made near the particle diameter of maximum penetration. Larger sized particles are expected to be filtered at a higher level. However, prior to this project, actual quantification of canister efficiency on bioaerosol challenges and for 1-5  $\mu\text{m}$  aerosol particles had either not been carried out or had not been carried out with sufficient quantification.
- In Phase I of the program, a literature search was performed on the efficiency of HEPA-grade canisters for micron-sized aerosol particles. Very few studies of HEPA canisters were found that addressed larger-sized particles and, in the few studies that did, the quantification was not sufficient to determine levels of efficiency above approximately 99.99%.
- Phase I also included dose calculations based on breathing rates, a range of possible field concentrations and exposure times. These calculations were performed for a range of respirator canister efficiencies and showed that penetrations on the order of  $10^{-7}$  (efficiencies on the order of 99.99999%) were needed to have zero particle penetration under the worst-case conditions.
- In Phase II of the program, direct measurements were made of filtration efficiency for the canisters for aerosols in the 1-5  $\mu\text{m}$  range. The canisters were challenged with aerosolized BG spores (the spore form of the microorganism *Bacillus atrophaeus* formerly *Bacillus globigii* or BG). The BG spore of approximately 1  $\mu\text{m}$  diameter and inert particles over a range of sizes from 0.3 – 10  $\mu\text{m}$ . The inert aerosol results provide a means of estimating canister penetration for bioaerosols having sizes different from the BG spores used in the tests. Canister flow rates ranged from 15 to 80 lpm.
- Key conclusions and observations are:
  - The maximum penetration for the aerosolized BG spores was  $< 2.5 \times 10^{-7}$  (efficiencies  $> 99.99997\%$ ). In 31 of 33 bioaerosol tests, zero BG spores were measured downstream of the test canister; the other two tests had counts of 1 and

3 BG spores. When no penetrating particles were counted, a 1 count was used to establish “less than” values for penetration (thus, the  $<2.5 \times 10^{-7}$  value above is based on minimum detection level; zero downstream counts were observed).

- The inert aerosol tests showed rapidly decreasing penetration as particle size increased above  $0.3 \mu\text{m}$ :
  - At  $0.3 - 0.4 \mu\text{m}$ , all canisters had efficiencies near their rated value (i.e., penetrations on the order of  $10^{-5}$  (efficiencies on the order of 99.999%).
  - At  $0.7 - 1.0 \mu\text{m}$ , the maximum penetration was  $< 1.4 \times 10^{-7}$  (efficiency  $>99.999986\%$ ) based on minimum detection limits. Many penetration measurements for this size range were on the order of  $10^{-8} - 10^{-9}$ . These results are consistent with the BG spore results.
  - At  $1 - 5 \mu\text{m}$ , penetrations were entirely based on detection limits (i.e., no counts were observed above background levels) and ranged from approximately  $< 10^{-7}$  to  $< 10^{-8}$ .
- The bioaerosol and inert aerosol results were consistent with each other with both showing penetrations on the order of  $<10^{-7} - <10^{-8}$  for particles in the  $0.7 - 1 \mu\text{m}$  size range.
- It must be noted that the respirator canister is only one component of the respirator system. Leakage at other parts of the system, such as face seal and exhalation valve, will often limit the overall level of protection.

# Validation of Respirator Filter Efficacy

## Final Report

### 1.0 Introduction

The program's objective was to characterize, validate and document the filtration efficiency of military gas mask canisters for use within high concentration biologically contaminated environment. The overall intent was to baseline the C2A1, R57B-P100, and CP3N filter canisters for use within biologically contaminated environments.

The project was conducted in two phases. Phase I consisted of 1) a literature search for existing filtration efficiency data for HEPA respirator canisters from micrometer-sized particles; 2) preliminary experimental work to explore means of directly measuring the efficiency of the canisters for bioaerosol and micrometer-sized inert challenge aerosols; and 3) computing dose estimates for a range field conditions including contaminant concentration, breathing rates, and exposure times. The results of Phase I were reported in the Phase I report ("Validation of Respirator Filter Efficacy: Phase I Quick Look Report (Hanley et al, October 2002). The Phase I report is provided as a companion document to this report.

This report presents the results of the Phase II effort to directly measure the filtration efficiency of the HEPA respirator canisters for aerosolized BG spores and inert (i.e., non biological) micrometer-sized aerosol particles. The BG spores were approximately 1  $\mu\text{m}$  in diameter. The inert aerosol covered a range of sizes from 0.3 – 10  $\mu\text{m}$  and provided both a point of comparison to the bioaerosol results and a means of estimating canister penetration for bioaerosols having particle sizes different from the BG spores used in the tests.

Section 2 presents the methodology and results of the bioaerosol tests. Methods and results for the inert aerosol tests are presented in Section 3. Section 4 presents conclusions from both the Phase I and Phase II studies. Appendices A and B contain the bioaerosol and inert aerosol detailed test data, respectively.

### 2.0 Bioaerosol Test Methods and Results

#### 2.1 Bioaerosol Methodology

**BG spores:** The bioaerosol tests were conducted using the spore form of the microorganism *Bacillus atrophaeus* (formerly *Bacillus globigii* or BG). The BG spore is elliptically shaped with dimensions of ~0.7 - 0.8 X 1 - 1.5 $\mu\text{m}$ . The BG spores were aerosolized from aqueous suspension using a 24-jet Collison nebulizer. The output of the nebulizer was dried and charge-neutralized prior to introduction to the exposure chamber. The objective of the generation system was to produce a stable high concentration aerosol of individual BG spores. A 6-stage bioaerosol impactor was used during pretests to confirm that the spores were being generated as single spores as opposed to multi-spore clusters.

**Bioaerosol exposure chamber:** The exposure chamber (Figures 1 and 2) was an acrylic chamber with a working volume of 61 x 61 x 100 cm. The BG aerosol was introduced at the top

of the chamber at a flowrate of approximately 280 lpm. A rotating baffle ensured well-mixed conditions within the chamber.

Each run tested three respirator canisters and three chamber monitors operated simultaneously. The canisters were operated at one of the specified test flows (30 – 80 lpm). The chamber monitors were operated at a fixed rate of for all tests (8.42 lpm) and provided measurement of the challenge BG aerosol concentration.

**Challenge concentration:** The bioaerosol challenge in the chamber was sampled using 37mm 0.4 µm polycarbonate pore membrane filters in disposable air monitoring cassettes. Three cassettes were mounted directly above the respirator canisters. Using membrane filters, as opposed to depth filters, facilitated complete suspension of collected spores from the surface of the filter.

To quantify the chamber bioaerosol challenge concentration, each chamber monitor filter was placed in a sterile receptacle containing phosphate-buffered saline with 0.1% Tween 80 (detergent) and agitated to suspend the collected BG spores. Dilutions of the suspension were made as needed. Approximately 1% of this suspension was diluted and replicates were plated on tryptic soy agar. The plates were incubated at 32°C overnight. Colony forming units (CFUs) were counted shortly after mature growth was noted.

**Sampling of Penetrating BG Spores:** Each respirator canister was connected to a 142 mm sampler containing a 142 mm 0.4 µm polycarbonate pore membrane filter. The relatively large size of the membrane filter allowed the full canister flow (up to 80 lpm) to be passed through the membrane without excessive pressure drop. This also maximized measurement sensitivity because any spore that penetrated the canister would be captured and detected on the membrane filter. The number of spores collected on the 142 mm filters downstream of the canisters was determined by placing the filter directly on the surface of a tryptic soy agar plate.

After sampling, the sampler with the attached respirator canister was carried to the biosafety cabinet. The respirator canister was removed and the sampler carefully opened to prevent cross contamination from the exposed surfaces. The polycarbonate filter was removed from the sample holder using sterile forceps and placed directly on the 150mm agar plate.

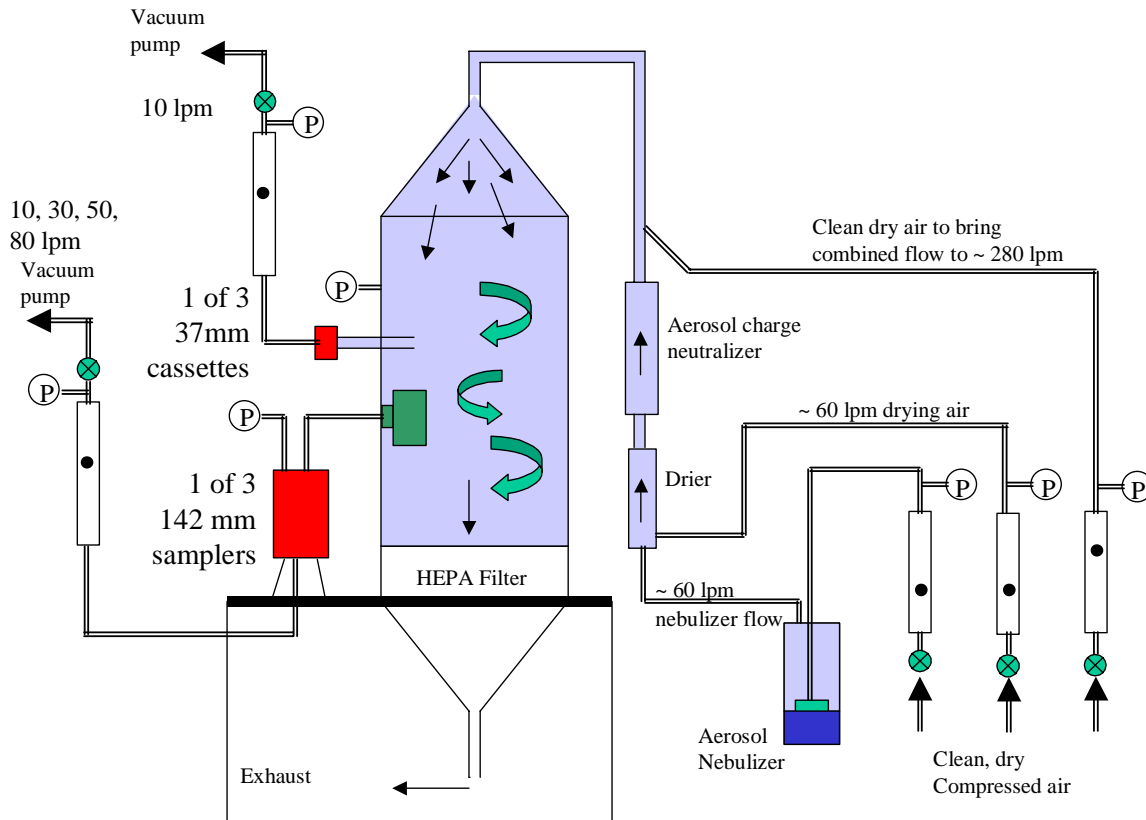
The test protocol consisted of the following steps:

- 1) Load a 142 mm membrane filter into the 142 mm filter holder
- 2) Sterilize the 142 mm filter holder with filter installed by autoclaving
- 3) Attach test canister to filter holder assembly in the biosafety cabinet
- 4) Attach the filter holder assemblies to the respirator test chamber
- 5) Turn on aerosol generation system and allow 10 minutes for stabilization
- 6) Turn on all samplers and do performance checks
- 7) Sample for 60 minutes
- 8) Turn off all pumps and aerosol generator
- 9) Flush the chamber with clean air
- 10) Transport filter holder assemblies with attached respirator canisters to biosafety cabinet

- 11) Open 142 mm filter holder
- 12) Transfer 142 mm filter to petri dish with media (allows detection limit of 1 CFU)

The plates were incubated at 32°C overnight. Colony forming units (CFUs) were counted shortly after mature growth was noted. Control tests for background level quantification were performed.

The protocol included several key steps taken in preparing and retrieving the bioaerosol samples to minimize the possibility of external contamination. The 142 mm filter holder with the membrane filter installed was sterilized prior to attaching the respirator canister by autoclaving at 121 °C for at least 15 min. All assembly of the test unit was in the biosafety cabinet. The test respirator canister was connected to and detached from the sampler only when located in the Class 2 biosafety cabinet. Sterile gloves were worn during the performance of each step.



**Figure 1. Schematic of bioaerosol test chamber. The BG spores were nebulized from an aqueous solution, dried and charge-neutralized followed by injection into the chamber. 37 mm samplers were used to monitor the chamber concentration and 142 mm samplers captured any spores penetrating the test canisters.**



**Calculation of Penetration and Efficiency:** From the chamber monitors and 142 mm penetration filters, the penetration was computed as:

$$\text{Penetration} = \frac{\text{CFU/m}^3 \text{ from 142 mm filter (through respirator canister)}}{\text{CFU/m}^3 \text{ from 37 mm filter (bioaerosol challenge in chamber)}}$$

The efficiency was calculated as:

$$\text{Efficiency (\%)} = 100 \times (1 - \text{Penetration})$$



**Figure 2. Photograph of bioaerosol test chamber. Samplers with canisters attached were assembled under a biosafety cabinet and then brought to the test chamber for attachment to side-wall ports. A clean hood was positioned over the samplers to minimize risk of sample contamination.**

**Figure 3. One of the 142 mm samplers with chamber mating flange and test canister attached.**



**Detection Limit:** When the downstream measurements were zero, a count of 1 CFU was used to establish the minimum detection limit. BG spores were detected on only two of the 33 142 mm filter samples. One spore was detected downstream of a C2A1 run at 30 lpm. Three spores were isolated from the filter downstream of a R57B canister run at 15 lpm. All the other downstream filters were negative.

## 2.2 Bioaerosol Test Series

The bioaerosol tests were performed in triplicate with the exception of the C2A1 canister, where eight replicates were made.

**Table 1. BG Spore Test Series.**

Filters	Flow rate *	# of Tests
C2A1	80 lpm	8
CP3N	80 lpm	3
R57B	40 lpm	3
C2A1	50 lpm	3
CP3N	50 lpm	3
R57B	25 lpm	3
C2A1	30 lpm	3
CP3N	30 lpm	3
R57B	15 lpm	3

\* The R57B was run at half flow rate because it is worn in pairs.

## 2.3 Bioaerosol Results

The results of the BG spores tests are summarized in Table 2. The raw data is tabulated in Appendix A.

The first column lists the respirator canister type. The second column shows the flow in liters per minute at which the test was performed. The third column gives the highest or maximum BG spore challenge of all the tests at that particular flow rate. Because the BG spore suspensions had to be prepared daily to ensure that none of the spores had germinated into vegetative cells, the number of spores in the Collison nebulizer varied each day.

The final two columns show the lowest measured penetration and the maximum measured efficiency, respectively. When the counts on the 142 mm filter downstream of the respirator canister were zero, the minimum detection limit is shown as a less than (<) value. As stated before, when there were zero counts, a count of 1 was used to determine the minimum detection limit and to calculate the penetration.

**Table 2. Summary of the Bioaerosol Test Results.**

Canister	Flow (LPM)	Maximum BG Challenge CFU/m <sup>3</sup> air	Lowest Measured Penetration	Maximum measured Efficiency (%)
C2A1	30	$3.0 \times 10^7$	$1.8 \times 10^{-8}$	99.999998
	50	$2.4 \times 10^6$	$< 1.4 \times 10^{-7}$	$> 99.999986$
	80	$3.2 \times 10^6$	$< 6.5 \times 10^{-8}$	$> 99.999993$
CP3N	30	$2.2 \times 10^7$	$< 2.5 \times 10^{-8}$	$> 99.999998$
	50	$2.5 \times 10^6$	$< 1.3 \times 10^{-7}$	$> 99.999987$
	80	$8.8 \times 10^5$	$< 2.5 \times 10^{-7}$	$> 99.999975$
R57B	15	$2.4 \times 10^7$	$< 4.6 \times 10^{-8}$	$> 99.999995$
	25	$2.6 \times 10^7$	$< 2.5 \times 10^{-8}$	$> 99.999997$
	40	$2.4 \times 10^7$	$< 1.7 \times 10^{-8}$	$> 99.999998$

The results show that all three types of respirator canister were highly efficient. All of the efficiencies exceeded 99.99997 %. The small differences in the penetrations and efficiencies seen in the table above are due to differences in the concentration of the challenge aerosol not the respirator canisters.

### 3.0 Inert Aerosol Methodology and Results

#### 3.1 Inert Particle Test Methodology

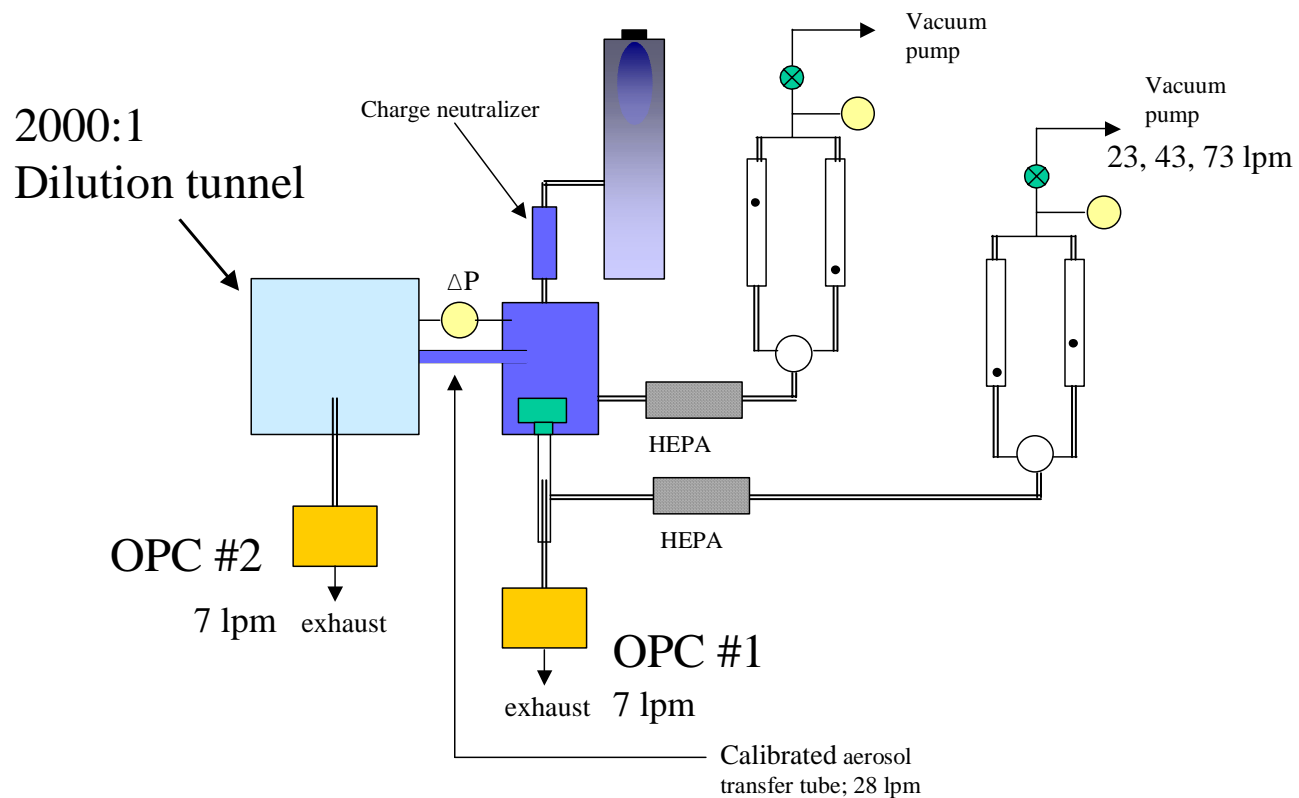
Inert particle testing was performed to extend the size range and measurement resolution of the bioaerosol measurements. The inert challenge was a polydisperse aerosol of dried, charge-neutral potassium chloride salt aerosol covering the range from 0.3 – 10  $\mu\text{m}$ . Aerosol concentrations upstream and downstream of the respirator were measured with a pair of aerosol particle counters (Climet Instruments Model CI-500 Spectrometer). The aerosol counters simultaneously counted and sized airborne particles in real time by drawing a continuous air sample through a detection chamber. The particle counters operate on the basis of light scattering, and each particle was individually counted and sized (at rates up to thousands per second) as it passes through a high intensity light beam. From these measurements, the filtration efficiency of the canisters was determined for 15 particle size ranges between 0.3 and 10  $\mu\text{m}$  as shown in Table 2.

**Table 2. Particle sizing channels of the OPC planned for the inert particle tests.**

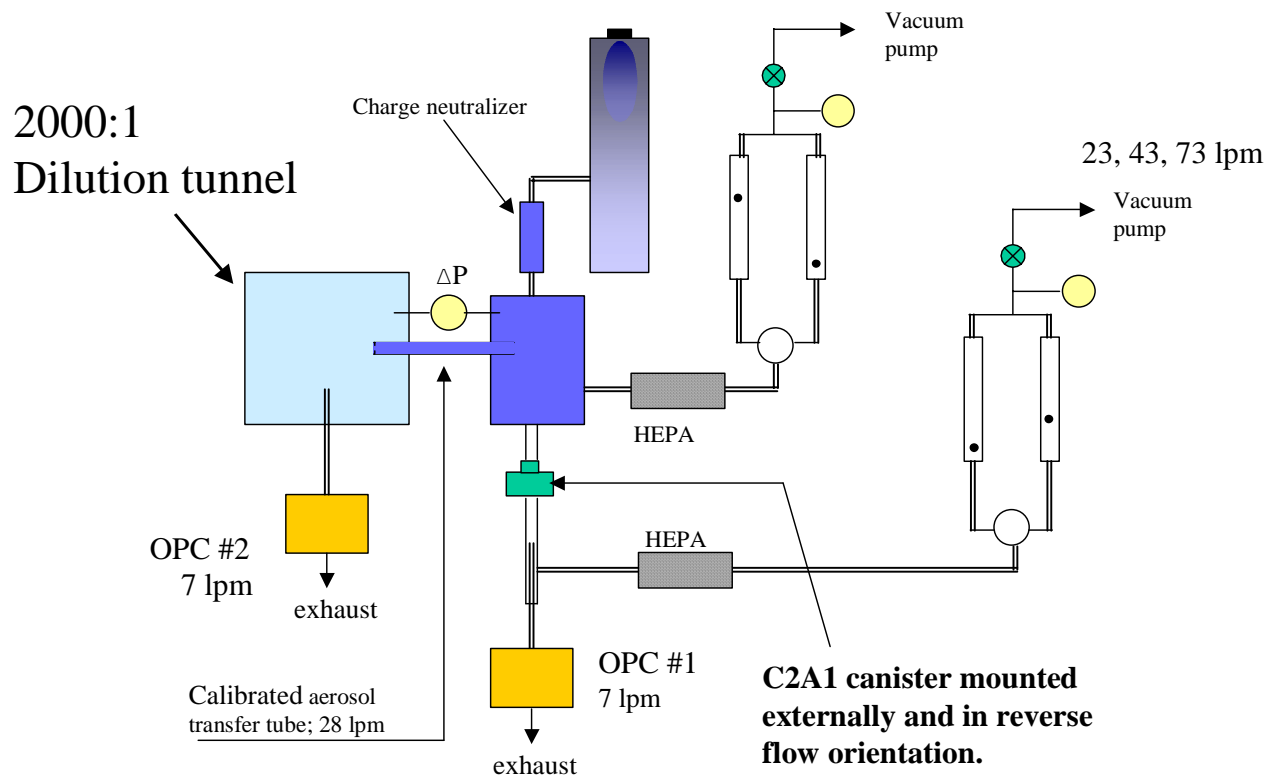
Channel No.	Size range ( $\mu\text{m}$ )	Channel No.	Size range ( $\mu\text{m}$ )
1	0.3 – 0.4	9	2.0 – 2.2
2	0.4 – 0.50	10	2.2 – 3
3	0.50 - 0.55	11	3 – 4
4	0.55 - 0.70	12	4 – 5
5	0.70 – 1.0	13	5 – 5.5
6	1.0 – 1.3	14	5.5- 7
7	1.3 – 1.6	15	7 – 10
8	1.6 – 2.0	-	-

**Test Chamber:** The tests were conducted by adding a canister exposure chamber to our standard ASHRAE 52.2 test rig (Figures 4 – 6). The rig (the dilution tunnel in the figures) is designed for testing HVAC filters over the 0.3 – 10  $\mu\text{m}$  size range (ASHRAE Standard 52.2-1999) with the KCl aerosol. To achieve a high concentration challenge, the output of the aerosol generator was directed to the canister exposure chamber. A side stream of this flow was then directed into the test duct. In this configuration, the ASHRAE test duct served as a dilution tunnel. Air from the canister test chamber flowed into the test duct at a measured rate of 28 lpm (1.0 cfm). This was combined with 56,000 lpm (2000 cfm) of particle-free airflow in the duct to provide a 2000:1 dilution ratio. Dilution of the challenge aerosol was needed to obtain on-scale readings with the challenge aerosol particle counter.

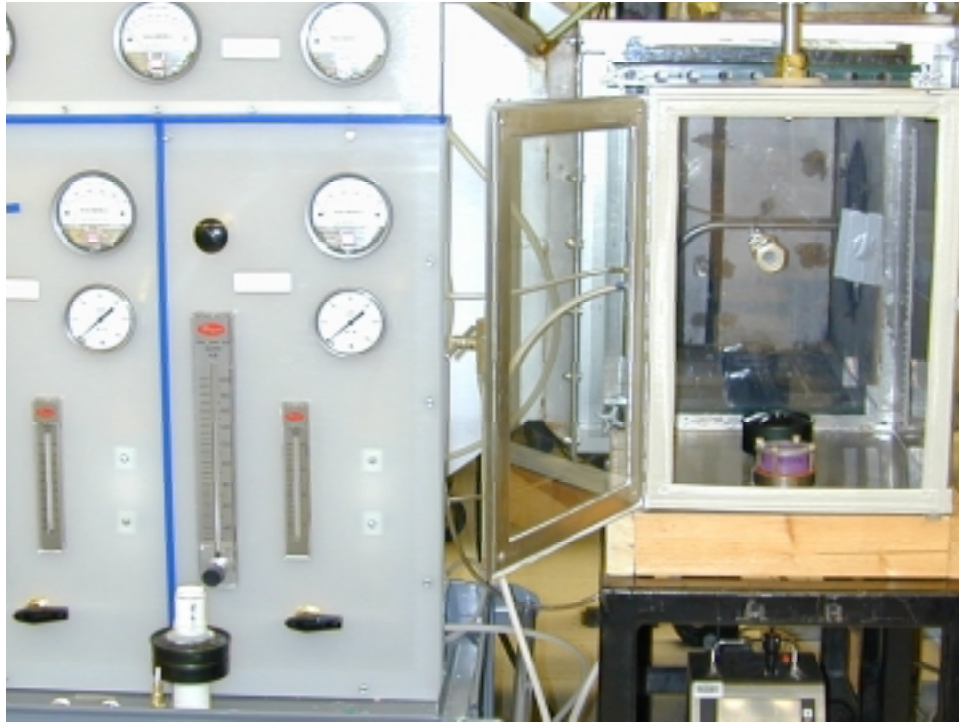
**Particle Counter Sampling:** The particle counters had at a fixed sample flow rate of 7.1 lpm. To sample the canister exhaust flow (ranging from 15 – 80 lpm) a sub sample was drawn from the air stream. The particle counter inlet probe inlet diameter and the diameter of the surrounding housing were selected to provide isokinetic sampling of the penetrating aerosol.



**Figure 4. Schematic of inert test system as used for the CP3N and R57B canisters. Aerosol was generated in a spray tower, dried, charge-neutralized and injected into the test chamber. A portion of the high concentration test chamber air was injected into clean air duct for dilution.**



**Figure 5. Schematic of inert test system as used for the C2A1 canister. The flow direction through the C2A1 was reversed and the canister was mounted external to the chamber.**



**Figure 6. Photo of inert test chamber (right) and sample control panel (left). The CP3N and R57B test canisters were installed within the chamber. Two different mounting fixtures were needed because of the different base design of the two canisters. Beneath the test chamber, the top portion of the particle counter is visible. The open end of the aerosol transfer tube is visible in the center of the back side of the chamber. A reverse-flow C2A1 canister with pipe thread attachments is seen on the left near the large rotameter.**

**Test Protocol:** The test protocol for full testing was as follows:

- 1) Install canister in exposure chamber
- 2) Obtain background counts by operating the full test system for 90 minutes with all airflows at test settings and the particle counters sampling the airstreams, but without aerosol generation; the last 60 minutes of this period was taken as the background count for the canister.
- 3) Begin aerosol generation.
- 4) After allowing 15 minutes for the aerosol generator to stabilize, begin 60 minutes of data collection – these counts are taken as the penetrating counts for the canister.

For the penetrating aerosol samples, each particle counter sample was 24 seconds duration with 150 samples collected per hour. The summation of these counts, after correction for background count and the fraction of flow sampled, provided the total penetrating particle count.

For the upstream aerosol concentration, the particle counter sampled via the dilution duct. Each sample was 24 seconds in duration but, unlike the penetrating aerosol samples, the challenge samples were taken at 10-minute intervals to prevent undue contamination of the counter. The average of these readings (after allowing the 15 minutes for the aerosol generator to stabilize) was computed and multiplied by 150 to provide the challenge particle count. This value was then multiplied by the dilution ratio (2000) to provided the total challenge counts for the 60-minute period.

Penetration and efficiency were then computed as:

$$\text{Penetration} = \frac{(\text{downstream counts} - \text{background counts}) \times (\text{canister flowrate} / \text{sample flowrate})}{\text{challenge counts} \times \text{dilution ratio}}$$

$$\text{Efficiency (\%)} = 100 \times (1 - \text{Penetration})$$

The calculations of penetration and efficiency were performed on a channel-by-channel basis for the 15 channels of the particle counters.

**Test protocol for screening tests:** The purpose of the screening tests was to see if any of the canisters had substantially higher penetration than the others thereby indicating the presence of a defect (e.g., a significant leak). For these tests, a clean-air purge line was added to the test system so that the canisters could be changed out without having the high concentration aerosol enter the downstream sampling system. For the screening tests, the procedure was:

- 1) Activate a clean-air purge flow in the particle counter sampling system
- 2) Install canister in exposure chamber
- 3) Turn off the clean-air purge flow
- 4) Immediately expose to aerosol and collect downstream counts for 5 minutes.
- 5) Activate the clean-air purge flow.



- 6) Remove canister and install the next one.

During these tests, the challenge aerosol particle counter sampling from the dilution tunnel ran continuously. For these screening tests, background counts were not obtained.

**Special procedure for C2A1 canister:** An unexpected problem was encountered with the test method for the C2A1 canister. This canister appears to have a relatively high rate of “particle shedding”, i.e., the canister appears to readily release particles into the downstream flow that come off of its internal components. One likely source of such particles was the granular activated carbon; carbon is known to often produce a fine powder dust, but other sources may be present. It is important to note that these particles do not represent penetration of the canister by the challenge aerosol, and thus should be subtracted from the total penetrating counts. The intention of our test protocol was to use the background counts measured in the 60 minutes prior to turning on the aerosol generator to correct for this type of particle source. However, for the C2A1, this was not adequate. While we do not fully understand the process, it may be that the shedding rate of the canister increased when a challenge aerosol was present through a cascading effect where one penetrating particle knocks off one or more “dust” particles into the air stream. While we don’t normally think of sub-micron particles having this effect (because of their low mass), given the high number of penetrating particles (on the order of 10,000 – 50,000 penetrating particles during the 1-hr test), it may be possible; it only took a few shedding particles to interfere with these high efficiency measurements.

Our solution to this problem was to isolate the source of the particles by running the C2A1 canister backwards with the flow entering the exit side and discharging through the inlet side. With this reversed flow, the carbon bed and the side of the HEPA media near the carbon bed were now upstream and any particle generation from these components would have to penetrate the HEPA media before showing up in the downstream counts. When tested in this manner, the C2A1 penetration counts were greatly reduced.

In order to run the canister with reverse flow, pipe thread fittings were attached (with hot-glue) to the inlet and outlet of the canister. Furthermore, in this configuration, the canisters had to be mounted on the outside of the exposure chamber as illustrated in Figure 5.

Note that such particle shedding would not be a problem in the bioaerosol tests. In the bioaerosol tests, the detection method only detected viable BG spores. Other non-biological particles would not appear as colony forming units in the samples.

**Detection Limit:** Due to non-zero background counts observed for many of the canisters, especially at the smaller particle sizes, a minimum detection limit was set at twice the background count or 1 particle, whichever was greater, for the CP3N and R57B canisters. Penetration values based on the minimum detection limit are reported as “less than” values.

For the C2A1 canister, higher background values and variability were observed than with the other canister types, even when operated with reverse flow. Thus, for the C2A1 tests, the minimum detection limit was taken as twice the background rate or 4 particles, whichever was greater. The data tables in Appendix B note these areas of high background variability.

For the one C2A1 canister test performed at 30 lpm with reverse flow, the canister had been previously used in one of the screening tests. Reusing the canister was necessary because all remaining new canisters had been used in tests directed at resolving the C2A1 shedding issue. Because the screening tests were performed in the normal flow orientation, the reverse flow test was susceptible to elevated shedding due to the previously collected inert test particles. Thus, for this test, only data below 0.7  $\mu\text{m}$  appeared reasonable; at larger particle sizes shedding of the previously deposited screening test particles precluded reliable penetration measurement.

When comparing “less than” values, note that it is not possible to rank the penetrations. All that can be said is that each individual value is less than the detection limit for that calculation. For example, the actual value of a “less than” entry could range from just slightly below the detection level to many orders of magnitude lower.

Typical challenge levels and the associated detection levels shown in Table 3.

**Table 3. Typical inert challenge counts and detection limits on penetration and efficiency; 1-hour test @ 80 lpm canister flow.**

<b>OPC Channel Number</b>	<b>Geo. Mean Diam. (<math>\mu\text{m}</math>)</b>	<b>Challenge counts</b>	<b>Penetration limit</b>	<b>Efficiency limit (%)</b>
1	0.35	3.4E+09	3.0E-10	99.99999997
2	0.45	2.4E+09	4.1E-10	99.99999996
3	0.52	4.8E+08	2.1E-09	99.99999979
4	0.62	1.2E+09	8.4E-10	99.99999992
5	0.84	2.2E+09	4.6E-10	99.99999995
6	1.14	8.2E+08	1.2E-09	99.99999988
7	1.44	3.9E+08	2.5E-09	99.99999975
8	1.79	3.2E+08	3.1E-09	99.99999969
9	2.10	1.5E+08	6.8E-09	99.99999932
10	2.57	3.8E+08	2.7E-09	99.99999973
11	3.46	1.9E+08	5.4E-09	99.99999946
12	4.47	7.4E+07	1.3E-08	99.99999866
13	5.24	2.4E+07	4.2E-08	99.99999578
14	6.20	3.5E+07	2.8E-08	99.99999716
15	8.37	1.4E+07	7.0E-08	99.99999300

### 3.2 Inert Aerosol Test series

The inert aerosol test series consisted of triplicate tests at the high flow rate and single tests at two lower flows (Table 3). Additionally, 25 screening tests of each canister type were performed at the high flow.

**Table 4. Inert Test Series**

Filter	Flow rate*	Round 1	Round 2	Round 3
C2A1	80 lpm	X	X	X
CP3N	80 lpm	X	X	X
R57B	40 lpm	X	X	X
C2A1	50 lpm	X		
CP3N	50 lpm	X		
R57B	25 lpm	X		
C2A1	30 lpm	X		
CP3N	30 lpm	X		
R57B	15 lpm	X		
Inert aerosol penetration screening tests:				
C2A1	80 lpm	25 canisters were screened; canisters with high penetration (if any) to be tested further.		
CP3N	80 lpm	25 canisters were screened; canisters with high penetration (if any) to be tested further.		
R57B	40 lpm	25 canisters were screened; canisters with high penetration (if any) to be tested further.		

\* Because the R57B canister is worn in pairs, its test flow rate was ½ that used for the other two canisters.

### 3.3 Inert Aerosol Tests Results

Results for the inert aerosol tests are summarized in Table 5 for the full tests of the canisters and provides penetration determinations from 0.3 – 10 µm. When the penetrating counts were zero or less than the background counts, the minimum detection level is used to report penetration as a “less than” value.

The penetration results are plotted in Figures 7 - 9 for the C2A1, CP3N, and R57B, respectively. In these figures, only measurements above the minimum detection level are shown. Figure 10 plots the average penetration of each canister at the high test flow (80 lpm for the C2A1 and CP3N and 40 lpm for the R57B).

Tables 6 - 8 show the results from the screening tests. In the tables, both the computed penetration (left side) and raw downstream counts (right side) are reported. The purpose of these tests was to see if any of the canisters had substantially higher penetration than the others thereby indicating the presence of a flaw (i.e., a significant leak). None of the canisters displayed leakage sufficient to be detected by the screening tests. Note that the screening tests did not quantify the background count rate and thus, background counts were not subtracted from the penetration counts. Thus, the penetrations shown are likely higher than actual because the background count rates were often non-zero over the 0.3 – 1  $\mu\text{m}$  size range, especially immediately after installing the canister. For the screening tests, the C2A1 was tested in its normal flow orientation and was installed inside the exposure chamber.

#### 4. Conclusions and Observations

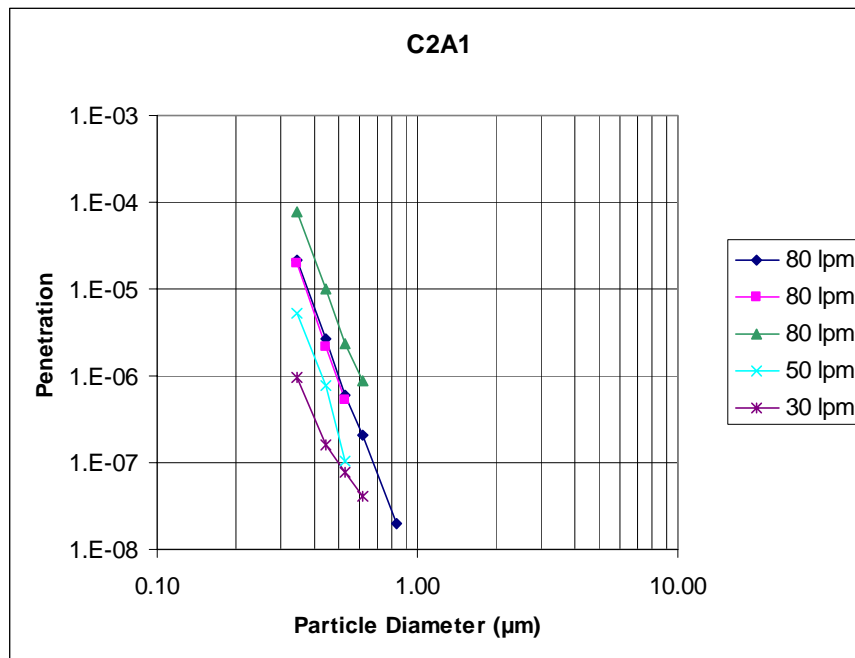
Key conclusions and observations are:

- The maximum penetration for the aerosolized BG spores was  $< 2.5 \times 10^{-7}$  (efficiencies  $> 99.99997\%$ ). In 31 of 33 bioaerosol tests, zero BG spores were measured downstream of the test canister; the other two tests had counts of 1 and 3 BG spores. When no penetrating particles were counted, a 1 count was used to establish “less than” values for penetration (thus, the  $< 2.5 \times 10^{-7}$  value above is based on minimum detection level; zero downstream counts were observed).
- The inert aerosol tests showed rapidly decreasing penetration as particle size increased above 0.3  $\mu\text{m}$ :
  - At 0.3 – 0.4  $\mu\text{m}$ , all canisters had efficiencies near their rated value (i.e., penetrations on the order of  $10^{-5}$  (efficiencies on the order of 99.999%).
  - At 0.7 – 1.0  $\mu\text{m}$ , the maximum penetration was  $< 1.4 \times 10^{-7}$  (efficiency  $> 99.999986\%$ ) based on minimum detection limits. Many penetration measurements for this size range were on the order of  $10^{-8}$  –  $10^{-9}$ .
  - At 1 – 5  $\mu\text{m}$ , penetrations were entirely based on detection limits (i.e., no counts were observed above background levels) and ranged from approximately  $< 10^{-7}$  to  $< 10^{-8}$ .
- The bioaerosol and inert aerosol results were consistent with each other with both showing penetrations on the order of  $< 10^{-7}$  -  $< 10^{-8}$  for particles in the 0.7 – 1  $\mu\text{m}$  size range.
- The inert aerosol results provide a means of estimating canister penetration for bioaerosols having sizes different from the BG spores used in the tests.
- It must be noted that the respirator canister is only one component of the respirator system. Leakage at other parts of the system, such as face seal and exhalation valve, will often limit the overall level of protection.

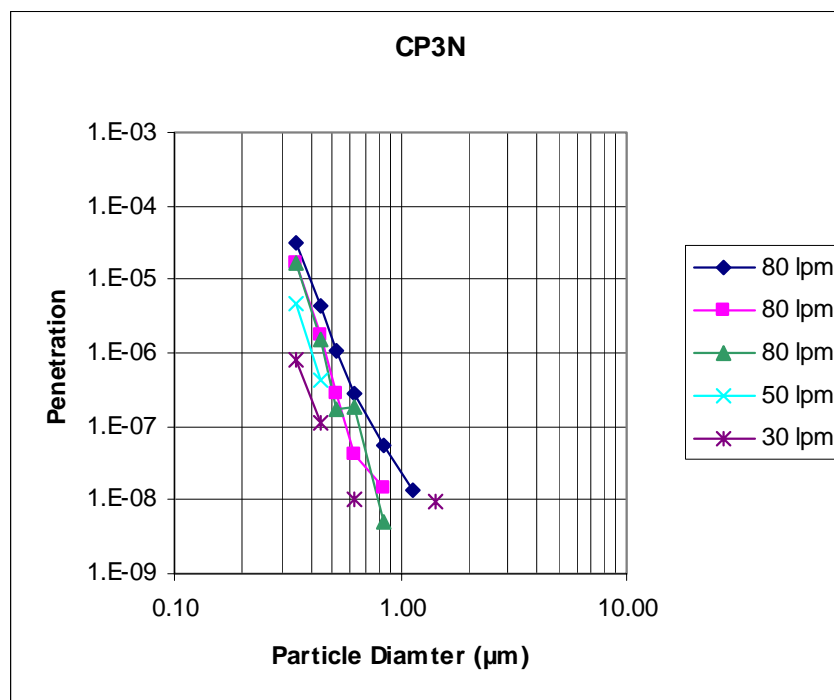
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**Table 5. Summary of inert aerosol test results. Values based on the minimum detection limits are reported as “less than” values.**

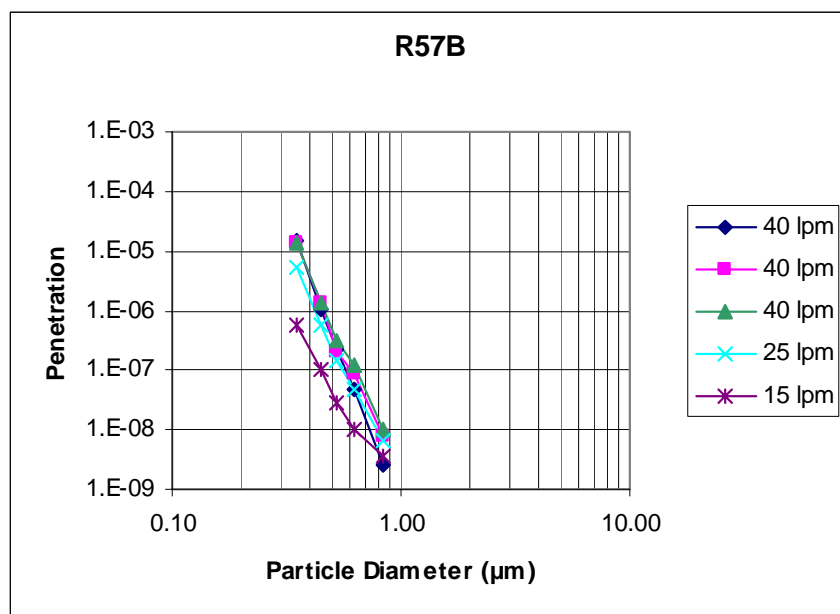
OPC Channel Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
Min. Diam (µm)	0.3	0.4	0.5	0.55	0.7	1	1.3	1.6	2	2.2	3	4	5	5.5	7		
Max. Diam (µm)	0.4	0.50	0.55	0.70	1.00	1.30	1.60	2.00	2.20	3.00	4.00	5.00	5.50	7.00	10.00		
Geo. Mean Diam. (µm)	0.35	0.45	0.52	0.62	0.84	1.14	1.44	1.79	2.10	2.57	3.46	4.47	5.24	6.20	8.37		
RTI Test No.	Canister Type	Flow Rate (LPM)															
03020301	C2A1	80	2.2E-5	2.6E-6	6.0E-7	2.1E-7	2.0E-8	< 5.6E-8	< 1.2E-7	< 1.4E-7	< 3.1E-7	< 1.2E-7	< 2.7E-7	< 6.8E-7	< 2.0E-6	< 1.4E-6	< 3.9E-6
03030301	C2A1	80	1.9E-5	2.2E-6	5.4E-7	< 1.3E-7	< 1.4E-7	< 1.1E-7	< 3.5E-7	< 1.4E-7	< 3.1E-7	< 1.9E-7	< 2.7E-7	< 6.6E-7	< 2.0E-6	< 1.5E-6	< 3.9E-6
03030302	C2A1	80	7.7E-5	1.0E-5	2.3E-6	8.8E-7	< 1.5E-7	< 2.0E-7	< 1.8E-7	< 1.5E-7	< 3.2E-7	< 2.7E-7	< 2.8E-7	< 7.4E-7	< 2.3E-6	< 1.6E-6	< 3.9E-6
		Mean	3.9E-5	5.0E-6	1.2E-6	< 4.1E-7	< 1.1E-7	< 1.2E-7	< 2.2E-7	< 1.4E-7	< 3.1E-7	< 1.9E-7	< 2.7E-7	< 6.9E-7	< 2.1E-6	< 1.5E-6	< 3.9E-6
03030303	C2A1	50	5.4E-6	7.6E-7	1.0E-7	< 8.3E-8	< 7.2E-8	< 1.8E-7	< 3.1E-7	< 4.2E-7	< 2.1E-7	< 3.8E-7	< 3.5E-7	< 4.7E-7	< 1.4E-6	< 1.1E-6	< 8.6E-6
03030304	C2A1	30	9.5E-7	1.6E-7	7.7E-8	4.1E-8											
12310203	CP3N	80	3.2E-5	4.4E-6	1.1E-6	2.9E-7	5.6E-8	1.3E-8	< 2.7E-8	< 3.2E-8	< 6.6E-8	< 2.5E-8	< 5.0E-8	< 1.2E-7	< 3.3E-7	< 2.3E-7	< 4.9E-7
01140303	CP3N	80	1.7E-5	1.7E-6	2.8E-7	4.3E-8	1.4E-8	< 1.3E-8	< 2.7E-8	< 3.3E-8	< 7.3E-8	< 3.0E-8	< 6.5E-8	< 1.7E-7	< 5.1E-7	< 3.8E-7	< 9.5E-7
01150302	CP3N	80	1.6E-5	1.5E-6	1.7E-7	1.8E-7	5.2E-9	< 1.4E-8	< 2.9E-8	< 3.6E-8	< 7.9E-8	< 3.2E-8	< 6.5E-8	< 1.7E-7	< 5.0E-7	< 3.6E-7	< 9.1E-7
		Mean	2.2E-5	2.5E-6	5.2E-7	1.7E-7	2.5E-8	< 1.3E-8	< 2.8E-8	< 3.4E-8	< 7.2E-8	< 2.9E-8	< 6.0E-8	< 1.5E-7	< 4.5E-7	< 3.2E-7	< 7.9E-7
01100302	CP3N	50	4.8E-6	4.2E-7	< 1.1E-7	< 4.8E-8	< 7.9E-9	< 6.9E-9	< 1.4E-8	< 1.6E-8	< 3.5E-8	< 1.4E-8	< 2.7E-8	< 6.5E-8	< 1.9E-7	< 1.3E-7	< 3.0E-7
01140301	CP3N	30	7.9E-7	1.1E-7	< 1.7E-8	1.0E-8	< 1.9E-9	< 4.8E-9	< 9.7E-9	< 1.2E-8	< 2.6E-8	< 1.1E-8	< 2.1E-8	< 5.1E-8	< 1.5E-7	< 1.1E-7	< 2.7E-7
01090301	R57B	40	1.5E-5	1.1E-6	2.2E-7	4.6E-8	2.6E-9	< 7.4E-9	< 1.4E-8	< 1.6E-8	< 3.3E-8	< 1.2E-8	< 2.2E-8	< 5.0E-8	< 1.3E-7	< 9.2E-8	< 1.8E-7
01160301	R57B	40	1.3E-5	1.4E-6	2.0E-7	8.5E-8	7.8E-9	< 6.9E-9	< 1.4E-8	< 1.8E-8	< 3.8E-8	< 1.5E-8	< 3.0E-8	< 7.6E-8	< 2.4E-7	< 1.6E-7	< 3.9E-7
01160302	R57B	40	1.4E-5	1.4E-6	3.1E-7	1.2E-7	1.0E-8	< 7.2E-9	< 1.5E-8	< 1.8E-8	< 3.8E-8	< 1.5E-8	< 3.1E-8	< 7.6E-8	< 2.3E-7	< 1.8E-7	< 4.2E-7
		Mean	1.4E-5	1.3E-6	2.5E-7	8.3E-8	6.9E-9	< 7.2E-9	< 1.4E-8	< 1.7E-8	< 3.6E-8	< 1.4E-8	< 2.8E-8	< 6.7E-8	< 2.0E-7	< 1.4E-7	< 3.3E-7
01100303	R57B	25	5.5E-6	5.8E-7	1.5E-7	4.8E-8	6.6E-9	< 3.4E-9	< 6.8E-9	< 8.4E-9	< 1.8E-8	< 7.4E-9	< 1.4E-8	< 3.5E-8	< 9.7E-8	< 7.2E-8	< 1.6E-7
01130301	R57B	15	5.9E-7	1.0E-7	2.9E-8	1.1E-8	3.5E-9	< 1.5E-9	< 2.9E-9	< 3.5E-9	< 8.2E-9	< 3.4E-9	< 7.1E-9	< 1.8E-8	< 5.7E-8	< 4.3E-8	< 1.2E-7



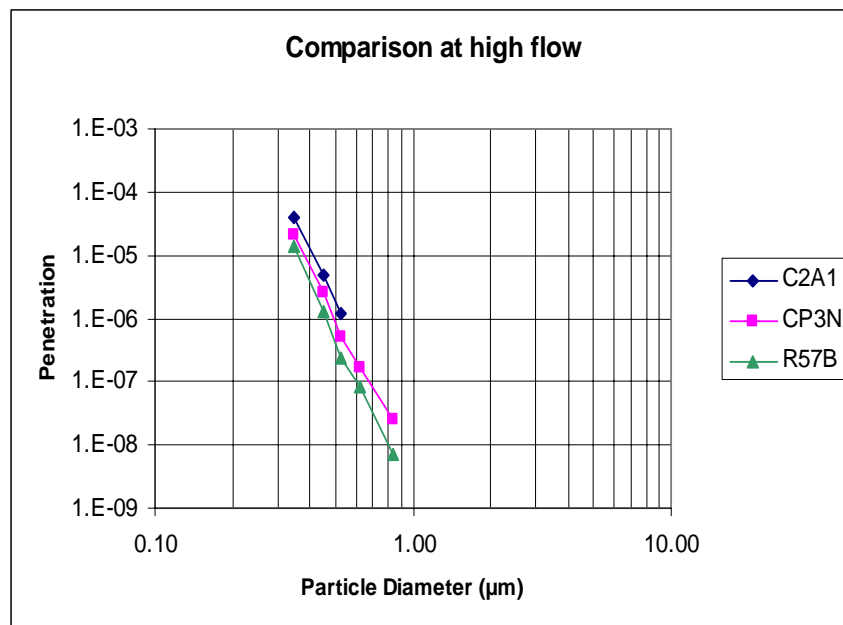
**Figure 7. Penetration curves for C2A1 canister at 30, 50 and 80 lpm.**



**Figure 8. Penetration curves for CP3N canister at 30, 50 and 80 lpm.**



**Figure 9. Penetration curves for R57B canister at 15, 25 and 40 lpm.**



**Figure 10. Comparison of the C2A1, CP3N and R57B at the high test flow rate.**



**Table 6. Screening results for C2A1 canisters.**

	Filtration Efficiency (%)					Raw Counts Observed				
	0.3 - 0.4	0.4 - 0.5	0.5-0.55	0.55-0.7	0.7-1	0.3 - 0.4	0.4 - 0.5	0.5-0.55	0.55-0.7	0.7-1
<b>1</b>	99.994	99.998	99.998	99.998	100.000	118	33	5	12	5
<b>2</b>	99.984	99.993	99.993	99.993	99.995	308	99	20	49	59
<b>3</b>	99.988	99.995	99.995	99.998	99.999	225	75	13	16	17
<b>4</b>	99.993	99.995	99.996	99.996	99.998	139	75	11	30	23
<b>5</b>	99.994	99.997	99.997	99.998	99.998	119	49	8	17	23
<b>6</b>	99.993	99.997	99.998	99.996	99.998	136	40	5	27	21
<b>7</b>	99.996	99.997	99.998	99.998	99.999	77	36	6	13	13
<b>8</b>	99.989	99.995	99.996	99.996	99.998	207	77	12	27	29
<b>9</b>	99.995	99.998	99.997	99.998	99.999	99	30	7	13	9
<b>10</b>	99.994	99.996	99.994	99.992	99.995	112	50	16	52	64
<b>11</b>	99.987	99.992	99.991	99.992	99.995	249	116	26	57	60
<b>12</b>	99.993	99.995	99.993	99.997	99.998	134	70	20	23	28
<b>13</b>	99.991	99.988	99.993	99.994	99.997	174	164	20	41	37
<b>14</b>	99.996	99.998	99.997	99.998	99.999	72	34	7	13	9
<b>15</b>	99.995	99.998	99.999	99.997	99.999	93	22	4	18	10
<b>16</b>	99.997	99.998	99.998	99.997	99.999	64	34	6	19	11
<b>17</b>	99.997	99.999	99.999	99.999	99.999	57	18	3	8	12
<b>18</b>	99.989	99.997	99.996	99.997	99.999	215	39	10	22	18
<b>19</b>	99.996	99.999	99.999	99.998	99.999	68	16	4	12	14
<b>20</b>	99.994	99.999	99.999	99.999	99.999	114	18	3	10	10
<b>21</b>	99.995	99.998	99.998	99.999	99.999	99	31	5	9	15
<b>22</b>	99.993	99.997	99.998	99.997	99.999	126	38	6	19	7
<b>23</b>	99.995	99.992	99.990	99.994	99.997	101	107	27	43	39
<b>24</b>	99.995	99.998	100.000	99.999	99.999	90	24	1	5	8
<b>25</b>	99.995	99.998	100.000	99.998	99.999	98	31	1	11	13

**Table 7. Screening results for the CP3N canisters**

	Filtration Efficiency (%)					Raw Counts Observed				
	0.3 - 0.4	0.4 - 0.5	0.5-0.55	0.55-0.7	0.7-1	0.3 - 0.4	0.4 - 0.5	0.5-0.55	0.55-0.7	0.7-1
<b>1</b>	99.998	100.000	100.000	100.000	100.000	43	4	0	1	0
<b>2</b>	99.986	99.993	99.995	99.997	99.999	267	96	13	24	17
<b>3</b>	99.992	99.999	99.999	100.000	100.000	148	17	2	0	1
<b>4</b>	99.992	99.999	100.000	100.000	100.000	158	18	1	0	1
<b>5</b>	99.992	99.999	100.000	100.000	100.000	145	14	0	0	0
<b>6</b>	99.990	99.998	100.000	99.999	100.000	190	33	0	4	0
<b>7</b>	99.994	99.999	100.000	100.000	100.000	121	11	0	1	0
<b>8</b>	99.992	99.999	99.999	100.000	100.000	153	14	2	3	0
<b>9</b>	99.994	99.999	99.999	100.000	100.000	105	21	2	0	0
<b>10</b>	99.994	99.999	100.000	100.000	100.000	118	11	1	0	0
<b>11</b>	99.995	99.999	100.000	100.000	100.000	101	16	0	1	0
<b>12</b>	99.996	99.999	99.999	100.000	100.000	85	8	2	2	0
<b>13</b>	99.994	99.999	100.000	100.000	100.000	115	16	0	1	0
<b>14</b>	99.995	99.999	100.000	100.000	100.000	99	13	1	1	0
<b>15</b>	99.995	99.999	100.000	100.000	100.000	104	10	1	0	0
<b>16</b>	99.993	99.999	100.000	100.000	100.000	131	17	0	1	1
<b>17</b>	99.994	99.999	100.000	99.999	100.000	109	8	0	4	0
<b>18</b>	99.995	99.999	100.000	100.000	100.000	103	15	1	1	0
<b>19</b>	99.995	100.000	100.000	100.000	100.000	101	6	0	0	0
<b>20</b>	99.989	99.998	99.999	100.000	100.000	202	24	2	1	1
<b>21</b>	99.993	99.999	100.000	100.000	100.000	140	19	0	1	0
<b>22</b>	99.993	99.999	99.999	100.000	100.000	135	12	3	0	0
<b>23</b>	99.994	99.999	100.000	100.000	100.000	122	8	0	0	0
<b>24</b>	99.994	99.998	99.999	100.000	100.000	113	23	2	1	2
<b>25</b>	99.993	99.999	100.000	100.000	100.000	130	17	1	1	0

**Table 8. Screening results for the R57B canisters**

	Filtration Efficiency (%)					Raw Counts Observed				
	0.3 - 0.4	0.4 - 0.5	0.5-0.55	0.55-0.7	0.7-1	0.3 - 0.4	0.4 - 0.5	0.5-0.55	0.55-0.7	0.7-1
<b>1</b>	99.994	99.999	100.000	100.000	100.000	130	9	0	1	0
<b>2</b>	99.974	99.992	99.993	99.996	99.998	591	127	23	32	33
<b>3</b>	99.991	99.999	100.000	100.000	100.000	208	15	1	0	0
<b>4</b>	99.991	99.999	100.000	100.000	100.000	205	10	1	0	0
<b>5</b>	99.993	99.999	99.999	100.000	100.000	154	11	3	0	0
<b>6</b>	99.988	99.998	100.000	100.000	100.000	265	25	1	0	0
<b>7</b>	99.993	99.999	100.000	100.000	100.000	155	13	1	1	0
<b>8</b>	99.990	99.999	100.000	100.000	100.000	213	14	1	1	1
<b>9</b>	99.993	99.999	100.000	100.000	100.000	151	15	0	0	0
<b>10</b>	99.993	99.999	100.000	100.000	100.000	159	11	1	1	0
<b>11</b>	99.995	100.000	100.000	100.000	100.000	105	7	0	1	0
<b>12</b>	99.991	99.999	100.000	100.000	100.000	195	15	1	0	0
<b>13</b>	99.993	99.999	100.000	100.000	100.000	161	17	1	0	0
<b>14</b>	99.993	99.999	100.000	100.000	100.000	151	9	0	0	0
<b>15</b>	99.997	100.000	100.000	100.000	100.000	75	5	1	0	0
<b>16</b>	99.992	99.999	100.000	100.000	100.000	179	9	0	1	0
<b>17</b>	99.993	99.999	100.000	100.000	100.000	151	13	0	1	0
<b>18</b>	99.993	100.000	100.000	100.000	100.000	153	8	0	0	0
<b>19</b>	99.993	99.999	99.999	100.000	100.000	149	18	2	1	0
<b>20</b>	99.998	100.000	100.000	100.000	100.000	40	4	0	0	0
<b>21</b>	99.991	99.999	100.000	100.000	100.000	196	15	0	0	0
<b>22</b>	99.993	99.999	100.000	100.000	100.000	160	22	1	1	0
<b>23</b>	99.991	99.999	100.000	100.000	100.000	195	20	0	2	0
<b>24</b>	99.994	99.999	100.000	100.000	100.000	143	18	1	0	0
<b>25</b>	99.994	100.000	100.000	100.000	100.000	144	5	0	0	0
1002	99.982	99.994	99.998	99.998	100.000	410	91	6	16	6

## **Appendix A**

### **Bioaerosol Test Data**

Pages 29 – 31 provide the raw data for the 37 mm chamber monitors and the calculation steps to compute the challenge BG spore concentrations (cfu/m<sup>3</sup> air).

Pages 32 - 33 provide the raw data for the 142 mm penetration filters located downstream of the test canisters and the calculation steps to compute the penetration BG spore concentration (cfu/m<sup>3</sup> air)

Pages 34 - 35 uses the above raw data to compute the penetration and efficiency values for each test.

date	filter	counts	mean	plated	recip dil	total ml	cfu/filter	min	flow lpm	cfu/m <sup>3</sup> air
<b>80 lpm</b>										
C2A1 canister										
12/30/2002	1	22 14	18	0.1	1000	5	9.0E+05	60	8.42	1.8E+06
	2	21 27	24	0.1	1000	5	1.2E+06	60	8.42	2.4E+06
	3	21 27	24	0.1	1000	5	1.2E+06	60	8.42	2.4E+06
CP3N canister										
12/31/2002	1	89 92	90.5	0.1	100	5	4.5E+05	61	8.42	8.8E+05
	2	57 78	67.5	0.1	100	5	3.4E+05	61	8.42	6.6E+05
	3	55 67	61	0.1	100	5	3.1E+05	61	8.42	5.9E+05
C2A1 canister										
1/3/2003	1	187 177	182	0.1	100	5	9.1E+05	60	8.42	1.8E+06
	2	181 172	176.5	0.1	100	5	8.8E+05	60	8.42	1.7E+06
C2A1 canister										
1/21/2003	1	321 317	319	0.1	100	5	1.6E+06	60	8.42	3.2E+06
	2	220 251	235.5	0.1	100	5	1.2E+06	60	8.42	2.3E+06
	3	316 330	323	0.1	100	5	1.6E+06	60	8.42	3.2E+06
<b>50 lpm</b>										
C2A1 canister										
1/2/2003	1	212 222	217	0.1	100	5	1.1E+06	60	8.42	2.1E+06
	2	161 205	183	0.1	100	5	9.2E+05	60	8.42	1.8E+06
	3	219 259	239	0.1	100	5	1.2E+06	60	8.42	2.4E+06

CP3N canister

1/2/2003	1	290 222	256	0.1	100	5	1.3E+06	60	8.42	2.5E+06
	2	214 238	226	0.1	100	5	1.1E+06	60	8.42	2.2E+06
	3	131 148	139.5	0.1	100	5	7.0E+05	60	8.42	1.4E+06

### 30 lpm

C2A1 canister

1/9/2003	1	271 273	272	0.1	1000	5	1.4E+07	60	8.42	2.7E+07
	2	270 334	302	0.1	1000	5	1.5E+07	60	8.42	3.0E+07
	3	282 219	250.5	0.1	1000	5	1.3E+07	60	8.42	2.5E+07

CP3N canister

1/9/2003	1	152 158	155	0.1	1000	5	7.8E+06	60.5	8.42	1.5E+07
	2	224 230	227	0.1	1000	5	1.1E+07	60.5	8.42	2.2E+07
	3	183 199	191	0.1	1000	5	9.6E+06	60.5	8.42	1.9E+07

### 40 lpm

R57B canister

1/13/2003	1	258 232	245	0.1	1000	5	1.2E+07	60	8.42	2.4E+07
	2	225 251	238	0.1	1000	5	1.2E+07	60	8.42	2.4E+07
	3	152 187	169.5	0.1	1000	5	8.5E+06	60	8.42	1.7E+07

### 25 lpm

R57B canister

1/13/2003	1	220 231	225.5	0.1	1000	5	1.1E+07	60	8.42	2.2E+07
	2	244 179	211.5	0.1	1000	5	1.1E+07	60	8.42	2.1E+07
	3	300 231	265.5	0.1	1000	5	1.3E+07	60	8.42	2.6E+07

## 15 lpm

R57B canister

1/14/2003	1	203 224	213.5	0.1	1000	5	1.1E+07	60	8.42	2.1E+07
	2	229 257	243	0.1	1000	5	1.2E+07	60	8.42	2.4E+07
	3	200 190	195	0.1	1000	5	9.8E+06	60	8.42	1.9E+07

date	filter	cfu/filter	min	flow lpm	cfu/m <sup>3</sup> air
<b>80 lpm</b>					
C2A1 canister					(I used because cannot use 0 to calculate)
12/30/2002	1	<i>I</i>	60	80	<0.21
	2	<i>I</i>	60	80	<0.21
	3	<i>I</i>	60	80	<0.21
CP3N canister					
12/31/2002	1	<i>I</i>	61	80	<0.20
	2	<i>I</i>	61	80	<0.20
	3	<i>I</i>	61	80	<0.20
double HEPA					
12/31/2002	1	<i>I</i>	60	80	<0.21
	2	<i>I</i>	60	80	<0.21
	3	<i>I</i>	60	80	<0.21
C2A1 canister					
1/3/2003	1	<i>I</i>	60	80	<0.21
	2	<i>I</i>	60	80	<0.21
C2A1 canister					
1/21/2003	1	<i>I</i>	60	80	<0.21
	2	<i>I</i>	60	80	<0.21
	3	<i>I</i>	60	80	<0.21
<b>50 lpm</b>					
C2A1 canister					
1/2/2003	1	<i>I</i>	60	50	<0.33
	2	<i>I</i>	60	50	<0.33
	3	<i>I</i>	60	50	<0.33
CP3N canister					



1/2/2003	1	<i>I</i>	60	50	<0.33
	2	<i>I</i>	60	50	<0.33
	3	<i>I</i>	60	50	<0.33

### 30 lpm

C2A1 canister

1/9/2003	1	<i>I</i>	60.5	30	<0.55
	2	1	60.5	30	0.551
	3	<i>I</i>	60.5	30	<0.55

CP3N canister

1/9/2003	1	<i>I</i>	60	30	<0.56
	2	<i>I</i>	60	30	<0.56
	3	<i>I</i>	60	30	<0.56

### 40 lpm

R57B canister

1/13/2003	1	<i>I</i>	60	40	<0.42
	2	<i>I</i>	60	40	<0.42
	3	<i>I</i>	60	40	<0.42

### 25 lpm

R57B canister

1/13/2003	1	<i>I</i>	60	25	<0.67
	2	<i>I</i>	60	25	<0.67
	3	<i>I</i>	60	25	<0.67

### 15 lpm

R57B canister

1/14/2003	1	<i>I</i>	60	15	<1.11
	2	<i>I</i>	60	15	<1.11
	3	3	60	15	3.33

	challenge downstream		Penetration	Efficiency (%)
	cfu/m <sup>3</sup> air	cfu/m <sup>3</sup> air		
<b>80 lpm</b>				
C2A1 canister				
12/30/2002 C2A1 canister - 1	1.8E+06	< 0.21	<1.17E-07	>99.999988
12/30/2002 C2A1 canister - 2	2.4E+06	< 0.21	<8.77E-08	>99.999991
12/30/2002 C2A1 canister - 3	2.4E+06	< 0.21	<8.77E-08	>99.999992
1/3/2003 C2A1 canister - 4	1.8E+06	< 0.21	<1.16E-07	>99.999988
1/3/2003 C2A1 canister - 5	1.7E+06	< 0.21	<1.19E-07	>99.999988
1/21/2003 C2A1 canister - 6	3.2E+06	< 0.21	<6.60E-08	>99.999993
1/21/2003 C2A1 canister - 7	2.3E+06	< 0.21	<8.94E-08	>99.999991
1/21/2003 C2A1 canister - 8	3.2E+06	< 0.21	<6.52E-08	>99.999993
CP3N canister				
12/31/2002 CP3N canister -1	8.8E+05	< 0.21	<2.36E-07	>99.999998
12/31/2002 CP3N canister -2	6.6E+05	< 0.21	<3.17E-07	>99.999997
12/31/2002 CP3N canister -3	5.9E+05	< 0.21	<3.51E-07	>99.999996
<b>40 lpm</b>				
R57B canister				
1/13/2003 R57B canister - 1	2.4E+07	< 0.42	<1.72E-08	>99.999998
1/13/2003 R57B canister - 2	2.4E+07	< 0.42	<1.77E-08	>99.999998
1/13/2003 R57B canister - 3	1.7E+07	< 0.42	<2.48E-08	>99.999998
<b>50 lpm</b>				
C2A1 canister				
1/2/2003 C2A1 canister - 9	2.1E+06	< 0.33	<1.55E-07	>99.999984
1/2/2003 C2A1 canister - 10	1.8E+06	< 0.33	<1.84E-07	>99.999982
1/2/2003 C2A1 canister - 11	2.4E+06	< 0.33	<1.41E-07	>99.999986
CP3N canister				
1/2/2003 CP3N canister - 4	2.5E+06	< 0.33	<1.32E-07	>99.999987
1/2/2003 CP3N canister - 5	2.2E+06	< 0.33	<1.49E-07	>99.999985
1/2/2003 CP3N canister - 6	1.4E+06	< 0.33	<2.41E-07	>99.999998
<b>25 lpm</b>				
R57B canister				
1/13/2003 R57B canister - 4	2.2E+07	< 0.67	<2.99E-08	>99.999997
1/13/2003 R57B canister - 5	2.1E+07	< 0.68	<3.18E-08	>99.999997
1/13/2003 R57B canister - 6	2.6E+07	< 0.69	<2.54E-08	>99.999997
<b>30 lpm</b>				
C2A1 canister				
1/9/2003 C2A1 canister - 12	2.7E+07	< 0.55	<2.05E-08	>99.999998
1/9/2003 C2A1 canister - 13	3.0E+07	0.55	1.84E-08	99.999998
1/9/2003 C2A1 canister - 14	2.5E+07	< 0.55	<2.22E-08	>99.999998
CP3N canister				
1/9/2003 CP3N canister - 7	1.5E+07	< 0.55	<3.62E-08	>99.999996

1/9/2003 CP3N canister - 8	2.2E+07	< 0.55	<2.47E-08	>99.999998
1/9/2003 CP3N canister - 9	1.9E+07	< 0.55	<2.94E-08	>99.999997

## 15 lpm

R57B canister

1/14/2003 R57B canister - 7	2.1E+07	< 1.11	<5.26E-08	>99.999994
1/14/2003 R57B canister - 8	2.4E+07	< 1.11	<4.62E-08	>99.999995
1/14/2003 R57B canister - 9	1.9E+07	3.33	1.73E-07	99.999998

## **Appendix B**

### **Inert Test Data**

The raw particle count data associated with each test is summarized along with the steps used to calculate the penetrations and filtration efficiencies.

Canister C2A1 Reverse Flow  
Flowrate (lpm) 80  
Test Number 03020301

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	3	6432	6429	11.3	72439.4	1,654,815	2,000	3,309,630,000	2.2E-05	99.997811	2.0E-08	99.999998	2.2E-05	99.997811
0.45	2	587	585	11.3	6591.5	1,260,345	2,000	2,520,690,000	2.6E-06	99.999739	1.8E-08	99.999998	2.6E-06	99.999739
0.52	0	26	26	11.3	293.0	243,600	2,000	487,200,000	6.0E-07	99.999940	9.3E-08	99.999991	6.0E-07	99.999940
0.62	0	23	23	11.3	259.2	617,475	2,000	1,234,950,000	2.1E-07	99.999979	3.6E-08	99.999996	2.1E-07	99.999979
0.84	0	4	4	11.3	45.1	1,120,215	2,000	2,240,430,000	2.0E-08	99.999998	2.0E-08	99.999998	2.0E-08	99.999998
1.14	1	0	-1	11.3	-11.3	400,755	2,000	801,510,000	-1.4E-08	100.000001	5.6E-08	99.999994	5.6E-08	99.999994
1.44	0	2	2	11.3	22.5	189,285	2,000	378,570,000	6.0E-08	99.999994	1.2E-07	99.999988	1.2E-07	99.999988
1.79	0	0	0	11.3	0.0	159,660	2,000	319,320,000	0.0E+00	100.000000	1.4E-07	99.999986	1.4E-07	99.999986
2.10	0	0	0	11.3	0.0	71,985	2,000	143,970,000	0.0E+00	100.000000	3.1E-07	99.999969	3.1E-07	99.999969
2.57	0	2	2	11.3	22.5	181,335	2,000	362,670,000	6.2E-08	99.999994	1.2E-07	99.999988	1.2E-07	99.999988
3.46	0	1	1	11.3	11.3	84,435	2,000	168,870,000	6.7E-08	99.999993	2.7E-07	99.999973	2.7E-07	99.999973
4.47	0	0	0	11.3	0.0	33,240	2,000	66,480,000	0.0E+00	100.000000	6.8E-07	99.999932	6.8E-07	99.999932
5.24	0	0	0	11.3	0.0	11,070	2,000	22,140,000	0.0E+00	100.000000	2.0E-06	99.999796	2.0E-06	99.999796
6.20	0	0	0	11.3	0.0	15,810	2,000	31,620,000	0.0E+00	100.000000	1.4E-06	99.999857	1.4E-06	99.999857
8.37	2	0	-2	11.3	-22.5	5,715	2,000	11,430,000	-2.0E-06	100.000197	3.9E-06	99.999606	3.9E-06	99.999606

Canister C2A1 Reverse Flow  
Flowrate (lpm) 80  
Test Number 03030301

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	33	5705	5672	11.3	63909.9	1,647,495	2,000	3,294,990,000	1.9E-05	99.998060	2.3E-07	99.999977	1.9E-05	99.998060
0.45	9	496	487	11.3	5487.3	1,247,370	2,000	2,494,740,000	2.2E-06	99.999780	8.1E-08	99.999992	2.2E-06	99.999780
0.52	2	25	23	11.3	259.2	241,350	2,000	482,700,000	5.4E-07	99.999946	9.3E-08	99.999991	5.4E-07	99.999946
0.62	7	17	10	11.3	112.7	609,150	2,000	1,218,300,000	9.2E-08	99.999991	1.3E-07	99.999987	1.3E-07	99.999987
0.84	14	6	-8	11.3	-90.1	1,105,560	2,000	2,211,120,000	-4.1E-08	100.000004	1.4E-07	99.999986	1.4E-07	99.999986
1.14	4	1	-3	11.3	-33.8	412,080	2,000	824,160,000	-4.1E-08	100.000004	1.1E-07	99.999989	1.1E-07	99.999989
1.44	6	1	-5	11.3	-56.3	193,800	2,000	387,600,000	-1.5E-07	100.000015	3.5E-07	99.999965	3.5E-07	99.999965
1.79	2	2	0	11.3	0.0	162,015	2,000	324,030,000	0.0E+00	100.000000	1.4E-07	99.999986	1.4E-07	99.999986
2.10	1	0	-1	11.3	-11.3	72,840	2,000	145,680,000	-7.7E-08	100.000008	3.1E-07	99.999969	3.1E-07	99.999969
2.57	3	2	-1	11.3	-11.3	178,995	2,000	357,990,000	-3.1E-08	100.000003	1.9E-07	99.999981	1.9E-07	99.999981
3.46	1	2	1	11.3	11.3	84,255	2,000	168,510,000	6.7E-08	99.999993	2.7E-07	99.999973	2.7E-07	99.999973
4.47	1	1	0	11.3	0.0	33,930	2,000	67,860,000	0.0E+00	100.000000	6.6E-07	99.999934	6.6E-07	99.999934
5.24	1	2	1	11.3	11.3	11,055	2,000	22,110,000	5.1E-07	99.999949	2.0E-06	99.999796	2.0E-06	99.999796
6.20	1	1	0	11.3	0.0	14,805	2,000	29,610,000	0.0E+00	100.000000	1.5E-06	99.999848	1.5E-06	99.999848
8.37	1	1	0	11.3	0.0	5,805	2,000	11,610,000	0.0E+00	100.000000	3.9E-06	99.999612	3.9E-06	99.999612

Background noise precludes reliable penetration measurement

Canister C2A1 Reverse Flow  
Flowrate (lpm) 80  
Test Number 03030302

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	33	21911	21878	11.3	246512.7	1,603,110	2,000	3,206,220,000	7.7E-05	99.992311	2.3E-07	99.999977	7.7E-05	99.992311
0.45	6	2199	2193	11.3	24709.9	1,219,725	2,000	2,439,450,000	1.0E-05	99.998987	5.5E-08	99.999994	1.0E-05	99.998987
0.52	4	103	99	11.3	1115.5	237,735	2,000	475,470,000	2.3E-06	99.999765	1.9E-07	99.999981	2.3E-06	99.999765
0.62	5	97	92	11.3	1036.6	591,240	2,000	1,182,480,000	8.8E-07	99.999912	9.5E-08	99.999990	8.8E-07	99.999912
0.84	15	11	-4	11.3	-45.1	1,092,075	2,000	2,184,150,000	-2.1E-08	100.000002	1.5E-07	99.999985	1.5E-07	99.999985
1.14	7	2	-5	11.3	-56.3	393,465	2,000	786,930,000	-7.2E-08	100.000007	2.0E-07	99.999980	2.0E-07	99.999980
1.44	3	0	-3	11.3	-33.8	184,635	2,000	369,270,000	-9.2E-08	100.000009	1.8E-07	99.999982	1.8E-07	99.999982
1.79	1	0	-1	11.3	-11.3	153,090	2,000	306,180,000	-3.7E-08	100.000004	1.5E-07	99.999985	1.5E-07	99.999985
2.10	1	1	0	11.3	0.0	70,020	2,000	140,040,000	0.0E+00	100.000000	3.2E-07	99.999968	3.2E-07	99.999968
2.57	4	0	-4	11.3	-45.1	169,425	2,000	338,850,000	-1.3E-07	100.000013	2.7E-07	99.999973	2.7E-07	99.999973
3.46	2	2	0	11.3	0.0	81,210	2,000	162,420,000	0.0E+00	100.000000	2.8E-07	99.999972	2.8E-07	99.999972
4.47	1	0	-1	11.3	-11.3	30,510	2,000	61,020,000	-1.8E-07	100.000018	7.4E-07	99.999926	7.4E-07	99.999926
5.24	0	1	1	11.3	11.3	9,780	2,000	19,560,000	5.8E-07	99.999942	2.3E-06	99.999770	2.3E-06	99.999770
6.20	0	1	1	11.3	11.3	13,905	2,000	27,810,000	4.1E-07	99.999959	1.6E-06	99.999838	1.6E-06	99.999838
8.37	0	1	1	11.3	11.3	5,730	2,000	11,460,000	9.8E-07	99.999902	3.9E-06	99.999607	3.9E-06	99.999607

Background noise precludes reliable penetration measurement

Canister C2A1 Reverse Flow  
Flowrate (lpm) 50  
Test Number 03030303

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	3	2443	2440	7.0	17183.1	1,597,185	2,000	3,194,370,000	5.4E-06	99.999462	1.3E-08	99.999999	5.4E-06	99.999462
0.45	9	273	264	7.0	1859.2	1,222,665	2,000	2,445,330,000	7.6E-07	99.999924	5.2E-08	99.999995	7.6E-07	99.999924
0.52	3	10	7	7.0	49.3	235,650	2,000	471,300,000	1.0E-07	99.999990	9.0E-08	99.999991	1.0E-07	99.999990
0.62	7	9	2	7.0	14.1	592,575	2,000	1,185,150,000	1.2E-08	99.999999	8.3E-08	99.999992	8.3E-08	99.999992
0.84	11	3	-8	7.0	-56.3	1,073,730	2,000	2,147,460,000	-2.6E-08	100.000003	7.2E-08	99.999993	7.2E-08	99.999993
1.14	10	2	-8	7.0	-56.3	385,095	2,000	770,190,000	-7.3E-08	100.000007	1.8E-07	99.999982	1.8E-07	99.999982
1.44	8	0	-8	7.0	-56.3	181,305	2,000	362,610,000	-1.6E-07	100.000016	3.1E-07	99.999969	3.1E-07	99.999969
1.79	9	1	-8	7.0	-56.3	150,135	2,000	300,270,000	-1.9E-07	100.000019	4.2E-07	99.999958	4.2E-07	99.999958
2.10	2	1	-1	7.0	-7.0	66,900	2,000	133,800,000	-5.3E-08	100.000005	2.1E-07	99.999979	2.1E-07	99.999979
2.57	9	3	-6	7.0	-42.3	165,420	2,000	330,840,000	-1.3E-07	100.000013	3.8E-07	99.999962	3.8E-07	99.999962
3.46	4	2	-2	7.0	-14.1	79,845	2,000	159,690,000	-8.8E-08	100.000009	3.5E-07	99.999965	3.5E-07	99.999965
4.47	1	4	3	7.0	21.1	29,655	2,000	59,310,000	3.6E-07	99.999964	4.7E-07	99.999953	4.7E-07	99.999953
5.24	1	1	0	7.0	0.0	9,855	2,000	19,710,000	0.0E+00	100.000000	1.4E-06	99.999857	1.4E-06	99.999857
6.20	1	3	2	7.0	14.1	13,290	2,000	26,580,000	5.3E-07	99.999947	1.1E-06	99.999894	1.1E-06	99.999894
8.37	6	2	-4	7.0	-28.2	4,905	2,000	9,810,000	-2.9E-06	100.000287	8.6E-06	99.999139	8.6E-06	99.999139

Background noise precludes reliable penetration measurement



Canister C2A1 Reverse Flow  
Flowrate (lpm) 30  
Test Number 03030304

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	13	780	767	4.2	3240.8	1,702,005	2,000	3,404,010,000	9.5E-07	99.999905	3.2E-08	99.999997	9.5E-07	99.999905
0.45	0	99	99	4.2	418.3	1,285,920	2,000	2,571,840,000	1.6E-07	99.999984	6.6E-09	99.999999	1.6E-07	99.999984
0.52	0	9	9	4.2	38.0	248,145	2,000	496,290,000	7.7E-08	99.999992	3.4E-08	99.999997	7.7E-08	99.999992
0.62	0	12	12	4.2	50.7	625,335	2,000	1,250,670,000	4.1E-08	99.999996	1.4E-08	99.999999	4.1E-08	99.999996
0.84	2	16	14	4.2	59.2	1,129,650	2,000	2,259,300,000	2.6E-08	99.999997	7.5E-09	99.999999	2.6E-08	99.999997
1.14	0	10	10	4.2	42.3	402,210	2,000	804,420,000	5.3E-08	99.999995	2.1E-08	99.999998	5.3E-08	99.999995
1.44	0	7	7	4.2	29.6	188,175	2,000	376,350,000	7.9E-08	99.999992	4.5E-08	99.999996	7.9E-08	99.999992
1.79	0	7	7	4.2	29.6	152,595	2,000	305,190,000	9.7E-08	99.999990	5.5E-08	99.999994	9.7E-08	99.999990
2.10	0	7	7	4.2	29.6	69,360	2,000	138,720,000	2.1E-07	99.999979	1.2E-07	99.999988	2.1E-07	99.999979
2.57	0	20	20	4.2	84.5	171,510	2,000	343,020,000	2.5E-07	99.999975	4.9E-08	99.999995	2.5E-07	99.999975
3.46	2	13	11	4.2	46.5	77,880	2,000	155,760,000	3.0E-07	99.999970	1.1E-07	99.999989	3.0E-07	99.999970
4.47	0	11	11	4.2	46.5	29,610	2,000	59,220,000	7.8E-07	99.999922	2.9E-07	99.999971	7.8E-07	99.999922
5.24	0	6	6	4.2	25.4	9,420	2,000	18,840,000	1.3E-06	99.999865	9.0E-07	99.999910	1.3E-06	99.999865
6.20	1	4	3	4.2	12.7	12,495	2,000	24,990,000	5.1E-07	99.999949	6.8E-07	99.999932	6.8E-07	99.999932
8.37	7	15	8	4.2	33.8	5,025	2,000	10,050,000	3.4E-06	99.999664	5.9E-06	99.999411	5.9E-06	99.999411

Background noise precludes reliable penetration measurement

This canister had been used in the screening tests; all new canisters had been used. Because the screening test was performed in the normal flow direction and this efficiency test in the reverse direction, additional shedding of particles from the HEPA media was not unexpected. Only the results for the lower particle sizes appear reasonable.

Canister CP3N  
Flowrate (lpm) 80  
Test Number 12310203

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	0	10759	10759	11.3	121228.2	1,866,794	2,000	3,733,588,000	3.2E-05	99.996753	3.0E-09	100.000000	3.2E-05	99.996753
0.45	0	1077	1077	11.3	12135.2	1,370,349	2,000	2,740,698,000	4.4E-06	99.999557	4.1E-09	100.000000	4.4E-06	99.999557
0.52	0	51	51	11.3	574.6	259,442	2,000	518,884,000	1.1E-06	99.999889	2.2E-08	99.999998	1.1E-06	99.999889
0.62	0	34	34	11.3	383.1	662,522	2,000	1,325,044,000	2.9E-07	99.999971	8.5E-09	99.999999	2.9E-07	99.999971
0.84	0	12	12	11.3	135.2	1,200,684	2,000	2,401,368,000	5.6E-08	99.999994	4.7E-09	100.000000	5.6E-08	99.999994
1.14	0	1	1	11.3	11.3	421,193	2,000	842,386,000	1.3E-08	99.999999	1.3E-08	99.999999	1.3E-08	99.999999
1.44	0	0	0	11.3	0.0	207,029	2,000	414,058,000	0.0E+00	100.000000	2.7E-08	99.999997	2.7E-08	99.999997
1.79	0	0	0	11.3	0.0	176,890	2,000	353,780,000	0.0E+00	100.000000	3.2E-08	99.999997	3.2E-08	99.999997
2.10	0	0	0	11.3	0.0	85,711	2,000	171,422,000	0.0E+00	100.000000	6.6E-08	99.999993	6.6E-08	99.999993
2.57	0	0	0	11.3	0.0	223,125	2,000	446,250,000	0.0E+00	100.000000	2.5E-08	99.999997	2.5E-08	99.999997
3.46	0	0	0	11.3	0.0	112,683	2,000	225,366,000	0.0E+00	100.000000	5.0E-08	99.999995	5.0E-08	99.999995
4.47	0	0	0	11.3	0.0	47,347	2,000	94,694,000	0.0E+00	100.000000	1.2E-07	99.999988	1.2E-07	99.999988
5.24	0	0	0	11.3	0.0	16,961	2,000	33,922,000	0.0E+00	100.000000	3.3E-07	99.999967	3.3E-07	99.999967
6.20	0	0	0	11.3	0.0	25,028	2,000	50,056,000	0.0E+00	100.000000	2.3E-07	99.999977	2.3E-07	99.999977
8.37	0	0	0	11.3	0.0	11,484	2,000	22,968,000	0.0E+00	100.000000	4.9E-07	99.999951	4.9E-07	99.999951

Canister CP3N  
Flowrate (lpm) 80  
Test Number 01140303

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	11	5443	5432	11.3	61205.6	1,854,615	2,000	3,709,230,000	1.7E-05	99.998350	3.3E-08	99.999997	1.7E-05	99.998350
0.45	5	419	414	11.3	4664.8	1,363,320	2,000	2,726,640,000	1.7E-06	99.999829	2.1E-08	99.999998	1.7E-06	99.999829
0.52	0	13	13	11.3	146.5	262,020	2,000	524,040,000	2.8E-07	99.999972	2.2E-08	99.999998	2.8E-07	99.999972
0.62	0	5	5	11.3	56.3	655,560	2,000	1,311,120,000	4.3E-08	99.999996	8.6E-09	99.999999	4.3E-08	99.999996
0.84	0	3	3	11.3	33.8	1,178,760	2,000	2,357,520,000	1.4E-08	99.999999	4.8E-09	100.000000	1.4E-08	99.999999
1.14	0	0	0	11.3	0.0	440,085	2,000	880,170,000	0.0E+00	100.000000	1.3E-08	99.999999	1.3E-08	99.999999
1.44	0	0	0	11.3	0.0	210,600	2,000	421,200,000	0.0E+00	100.000000	2.7E-08	99.999997	2.7E-08	99.999997
1.79	0	0	0	11.3	0.0	169,350	2,000	338,700,000	0.0E+00	100.000000	3.3E-08	99.999997	3.3E-08	99.999997
2.10	0	0	0	11.3	0.0	77,700	2,000	155,400,000	0.0E+00	100.000000	7.3E-08	99.999993	7.3E-08	99.999993
2.57	0	0	0	11.3	0.0	185,130	2,000	370,260,000	0.0E+00	100.000000	3.0E-08	99.999997	3.0E-08	99.999997
3.46	0	0	0	11.3	0.0	86,385	2,000	172,770,000	0.0E+00	100.000000	6.5E-08	99.999993	6.5E-08	99.999993
4.47	0	0	0	11.3	0.0	33,780	2,000	67,560,000	0.0E+00	100.000000	1.7E-07	99.999983	1.7E-07	99.999983
5.24	0	0	0	11.3	0.0	10,980	2,000	21,960,000	0.0E+00	100.000000	5.1E-07	99.999949	5.1E-07	99.999949
6.20	0	0	0	11.3	0.0	14,715	2,000	29,430,000	0.0E+00	100.000000	3.8E-07	99.999962	3.8E-07	99.999962
8.37	0	0	0	11.3	0.0	5,910	2,000	11,820,000	0.0E+00	100.000000	9.5E-07	99.999905	9.5E-07	99.999905

Canister CP3N  
Flowrate (lpm) 80  
Test Number 01150302

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	18	4847	4829	11.3	54411.3	1,673,085	2,000	3,346,170,000	1.6E-05	99.998374	6.1E-08	99.999994	1.6E-05	99.998374
0.45	5	327	322	11.3	3628.2	1,221,900	2,000	2,443,800,000	1.5E-06	99.999852	2.3E-08	99.999998	1.5E-06	99.999852
0.52	1	8	7	11.3	78.9	233,535	2,000	467,070,000	1.7E-07	99.999983	2.4E-08	99.999998	1.7E-07	99.999983
0.62	0	19	19	11.3	214.1	591,195	2,000	1,182,390,000	1.8E-07	99.999982	9.5E-09	99.999999	1.8E-07	99.999982
0.84	1	2	1	11.3	11.3	1,089,060	2,000	2,178,120,000	5.2E-09	99.999999	5.2E-09	99.999999	5.2E-09	99.999999
1.14	0	0	0	11.3	0.0	400,035	2,000	800,070,000	0.0E+00	100.000000	1.4E-08	99.999999	1.4E-08	99.999999
1.44	0	0	0	11.3	0.0	193,605	2,000	387,210,000	0.0E+00	100.000000	2.9E-08	99.999997	2.9E-08	99.999997
1.79	0	0	0	11.3	0.0	155,700	2,000	311,400,000	0.0E+00	100.000000	3.6E-08	99.999996	3.6E-08	99.999996
2.10	0	0	0	11.3	0.0	71,250	2,000	142,500,000	0.0E+00	100.000000	7.9E-08	99.999992	7.9E-08	99.999992
2.57	0	0	0	11.3	0.0	178,305	2,000	356,610,000	0.0E+00	100.000000	3.2E-08	99.999997	3.2E-08	99.999997
3.46	0	0	0	11.3	0.0	86,385	2,000	172,770,000	0.0E+00	100.000000	6.5E-08	99.999993	6.5E-08	99.999993
4.47	0	0	0	11.3	0.0	32,820	2,000	65,640,000	0.0E+00	100.000000	1.7E-07	99.999983	1.7E-07	99.999983
5.24	0	0	0	11.3	0.0	11,265	2,000	22,530,000	0.0E+00	100.000000	5.0E-07	99.999950	5.0E-07	99.999950
6.20	0	0	0	11.3	0.0	15,510	2,000	31,020,000	0.0E+00	100.000000	3.6E-07	99.999964	3.6E-07	99.999964
8.37	0	0	0	11.3	0.0	6,165	2,000	12,330,000	0.0E+00	100.000000	9.1E-07	99.999909	9.1E-07	99.999909

Canister CP3N  
Flowrate (lpm) 50  
Test Number 01100302

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	48	2909	2861	7.0	20147.9	2,086,815	2,000	4,173,630,000	4.8E-06	99.999517	8.1E-08	99.999992	4.8E-06	99.999517
0.45	47	228	181	7.0	1274.6	1,526,595	2,000	3,053,190,000	4.2E-07	99.999958	1.1E-07	99.999989	4.2E-07	99.999958
0.52	9	13	4	7.0	28.2	294,480	2,000	588,960,000	4.8E-08	99.999995	1.1E-07	99.999989	1.1E-07	99.999989
0.62	10	10	0	7.0	0.0	737,265	2,000	1,474,530,000	0.0E+00	100.000000	4.8E-08	99.999995	4.8E-08	99.999995
0.84	3	2	-1	7.0	-7.0	1,342,860	2,000	2,685,720,000	-2.6E-09	100.000000	7.9E-09	99.999999	7.9E-09	99.999999
1.14	0	0	0	7.0	0.0	511,845	2,000	1,023,690,000	0.0E+00	100.000000	6.9E-09	99.999999	6.9E-09	99.999999
1.44	0	0	0	7.0	0.0	259,005	2,000	518,010,000	0.0E+00	100.000000	1.4E-08	99.999999	1.4E-08	99.999999
1.79	1	0	-1	7.0	-7.0	218,010	2,000	436,020,000	-1.6E-08	100.000002	1.6E-08	99.999998	1.6E-08	99.999998
2.10	0	0	0	7.0	0.0	99,375	2,000	198,750,000	0.0E+00	100.000000	3.5E-08	99.999996	3.5E-08	99.999996
2.57	0	0	0	7.0	0.0	254,820	2,000	509,640,000	0.0E+00	100.000000	1.4E-08	99.999999	1.4E-08	99.999999
3.46	0	0	0	7.0	0.0	129,180	2,000	258,360,000	0.0E+00	100.000000	2.7E-08	99.999997	2.7E-08	99.999997
4.47	0	0	0	7.0	0.0	53,925	2,000	107,850,000	0.0E+00	100.000000	6.5E-08	99.999993	6.5E-08	99.999993
5.24	0	0	0	7.0	0.0	18,765	2,000	37,530,000	0.0E+00	100.000000	1.9E-07	99.999981	1.9E-07	99.999981
6.20	0	0	0	7.0	0.0	26,295	2,000	52,590,000	0.0E+00	100.000000	1.3E-07	99.999987	1.3E-07	99.999987
8.37	0	0	0	7.0	0.0	11,610	2,000	23,220,000	0.0E+00	100.000000	3.0E-07	99.999970	3.0E-07	99.999970

Canister CP3N  
Flowrate (lpm) 30  
Test Number 01140301

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	21	681	660	4.2	2788.7	1,769,370	2,000	3,538,740,000	7.9E-07	99.999921	2.5E-08	99.999997	7.9E-07	99.999921
0.45	4	72	68	4.2	287.3	1,288,905	2,000	2,577,810,000	1.1E-07	99.999989	6.6E-09	99.999999	1.1E-07	99.999989
0.52	2	0	-2	4.2	-8.5	250,230	2,000	500,460,000	-1.7E-08	100.000002	1.7E-08	99.999998	1.7E-08	99.999998
0.62	0	3	3	4.2	12.7	620,070	2,000	1,240,140,000	1.0E-08	99.999999	3.4E-09	100.000000	1.0E-08	99.999999
0.84	0	0	0	4.2	0.0	1,120,875	2,000	2,241,750,000	0.0E+00	100.000000	1.9E-09	100.000000	1.9E-09	100.000000
1.14	0	0	0	4.2	0.0	443,235	2,000	886,470,000	0.0E+00	100.000000	4.8E-09	100.000000	4.8E-09	100.000000
1.44	0	1	1	4.2	4.2	217,575	2,000	435,150,000	9.7E-09	99.999999	9.7E-09	99.999999	9.7E-09	99.999999
1.79	0	0	0	4.2	0.0	179,625	2,000	359,250,000	0.0E+00	100.000000	1.2E-08	99.999999	1.2E-08	99.999999
2.10	0	0	0	4.2	0.0	81,585	2,000	163,170,000	0.0E+00	100.000000	2.6E-08	99.999997	2.6E-08	99.999997
2.57	0	0	0	4.2	0.0	200,940	2,000	401,880,000	0.0E+00	100.000000	1.1E-08	99.999999	1.1E-08	99.999999
3.46	0	0	0	4.2	0.0	102,360	2,000	204,720,000	0.0E+00	100.000000	2.1E-08	99.999998	2.1E-08	99.999998
4.47	0	0	0	4.2	0.0	41,580	2,000	83,160,000	0.0E+00	100.000000	5.1E-08	99.999995	5.1E-08	99.999995
5.24	0	0	0	4.2	0.0	14,160	2,000	28,320,000	0.0E+00	100.000000	1.5E-07	99.999985	1.5E-07	99.999985
6.20	0	0	0	4.2	0.0	19,170	2,000	38,340,000	0.0E+00	100.000000	1.1E-07	99.999989	1.1E-07	99.999989
8.37	0	0	0	4.2	0.0	7,800	2,000	15,600,000	0.0E+00	100.000000	2.7E-07	99.999973	2.7E-07	99.999973

Canister R57B  
Flowrate (lpm) 40  
Test Number 01090301

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	4	9092	9088	5.6	51200.0	1,711,440	2,000	3,422,880,000	1.5E-05	99.998504	6.6E-09	99.999999	1.5E-05	99.998504
0.45	0	488	488	5.6	2749.3	1,296,000	2,000	2,592,000,000	1.1E-06	99.999894	2.2E-09	100.000000	1.1E-06	99.999894
0.52	0	19	19	5.6	107.0	238,530	2,000	477,060,000	2.2E-07	99.999978	1.2E-08	99.999999	2.2E-07	99.999978
0.62	0	10	10	5.6	56.3	615,495	2,000	1,230,990,000	4.6E-08	99.999995	4.6E-09	100.000000	4.6E-08	99.999995
0.84	0	1	1	5.6	5.6	1,103,700	2,000	2,207,400,000	2.6E-09	100.000000	2.6E-09	100.000000	2.6E-09	100.000000
1.14	0	0	0	5.6	0.0	379,425	2,000	758,850,000	0.0E+00	100.000000	7.4E-09	99.999999	7.4E-09	99.999999
1.44	0	0	0	5.6	0.0	198,015	2,000	396,030,000	0.0E+00	100.000000	1.4E-08	99.999999	1.4E-08	99.999999
1.79	0	0	0	5.6	0.0	181,245	2,000	362,490,000	0.0E+00	100.000000	1.6E-08	99.999998	1.6E-08	99.999998
2.10	0	0	0	5.6	0.0	86,505	2,000	173,010,000	0.0E+00	100.000000	3.3E-08	99.999997	3.3E-08	99.999997
2.57	0	0	0	5.6	0.0	233,430	2,000	466,860,000	0.0E+00	100.000000	1.2E-08	99.999999	1.2E-08	99.999999
3.46	0	0	0	5.6	0.0	128,520	2,000	257,040,000	0.0E+00	100.000000	2.2E-08	99.999998	2.2E-08	99.999998
4.47	0	0	0	5.6	0.0	56,670	2,000	113,340,000	0.0E+00	100.000000	5.0E-08	99.999995	5.0E-08	99.999995
5.24	0	0	0	5.6	0.0	21,300	2,000	42,600,000	0.0E+00	100.000000	1.3E-07	99.999987	1.3E-07	99.999987
6.20	0	0	0	5.6	0.0	30,705	2,000	61,410,000	0.0E+00	100.000000	9.2E-08	99.999991	9.2E-08	99.999991
8.37	0	0	0	5.6	0.0	15,765	2,000	31,530,000	0.0E+00	100.000000	1.8E-07	99.999982	1.8E-07	99.999982

Canister R57B  
Flowrate (lpm) 40  
Test Number 01160301

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	10	8042	8032	5.6	45250.7	1,684,650	2,000	3,369,300,000	1.3E-05	99.998657	1.7E-08	99.999998	1.3E-05	99.998657
0.45	1	597	596	5.6	3357.7	1,219,635	2,000	2,439,270,000	1.4E-06	99.999862	2.3E-09	100.000000	1.4E-06	99.999862
0.52	0	17	17	5.6	95.8	238,275	2,000	476,550,000	2.0E-07	99.999980	1.2E-08	99.999999	2.0E-07	99.999980
0.62	0	18	18	5.6	101.4	595,650	2,000	1,191,300,000	8.5E-08	99.999991	4.7E-09	100.000000	8.5E-08	99.999991
0.84	0	3	3	5.6	16.9	1,085,775	2,000	2,171,550,000	7.8E-09	99.999999	2.6E-09	100.000000	7.8E-09	99.999999
1.14	0	0	0	5.6	0.0	407,985	2,000	815,970,000	0.0E+00	100.000000	6.9E-09	99.999999	6.9E-09	99.999999
1.44	0	0	0	5.6	0.0	196,695	2,000	393,390,000	0.0E+00	100.000000	1.4E-08	99.999999	1.4E-08	99.999999
1.79	0	0	0	5.6	0.0	160,485	2,000	320,970,000	0.0E+00	100.000000	1.8E-08	99.999998	1.8E-08	99.999998
2.10	0	0	0	5.6	0.0	73,560	2,000	147,120,000	0.0E+00	100.000000	3.8E-08	99.999996	3.8E-08	99.999996
2.57	0	0	0	5.6	0.0	188,175	2,000	376,350,000	0.0E+00	100.000000	1.5E-08	99.999999	1.5E-08	99.999999
3.46	0	0	0	5.6	0.0	92,640	2,000	185,280,000	0.0E+00	100.000000	3.0E-08	99.999997	3.0E-08	99.999997
4.47	0	0	0	5.6	0.0	37,230	2,000	74,460,000	0.0E+00	100.000000	7.6E-08	99.999992	7.6E-08	99.999992
5.24	0	0	0	5.6	0.0	11,835	2,000	23,670,000	0.0E+00	100.000000	2.4E-07	99.999976	2.4E-07	99.999976
6.20	0	0	0	5.6	0.0	17,580	2,000	35,160,000	0.0E+00	100.000000	1.6E-07	99.999984	1.6E-07	99.999984
8.37	0	0	0	5.6	0.0	7,140	2,000	14,280,000	0.0E+00	100.000000	3.9E-07	99.999961	3.9E-07	99.999961



Canister R57B  
Flowrate (lpm) 40  
Test Number 01160302

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	7	8204	8197	5.6	46180.3	1,676,820	2,000	3,353,640,000	1.4E-05	99.998623	1.2E-08	99.999999	1.4E-05	99.998623
0.45	2	608	606	5.6	3414.1	1,223,850	2,000	2,447,700,000	1.4E-06	99.999861	4.6E-09	100.000000	1.4E-06	99.999861
0.52	0	26	26	5.6	146.5	234,375	2,000	468,750,000	3.1E-07	99.999969	1.2E-08	99.999999	3.1E-07	99.999969
0.62	0	25	25	5.6	140.8	594,300	2,000	1,188,600,000	1.2E-07	99.999988	4.7E-09	100.000000	1.2E-07	99.999988
0.84	0	4	4	5.6	22.5	1,086,165	2,000	2,172,330,000	1.0E-08	99.999999	2.6E-09	100.000000	1.0E-08	99.999999
1.14	0	0	0	5.6	0.0	393,420	2,000	786,840,000	0.0E+00	100.000000	7.2E-09	99.999999	7.2E-09	99.999999
1.44	0	0	0	5.6	0.0	192,180	2,000	384,360,000	0.0E+00	100.000000	1.5E-08	99.999999	1.5E-08	99.999999
1.79	0	0	0	5.6	0.0	159,345	2,000	318,690,000	0.0E+00	100.000000	1.8E-08	99.999998	1.8E-08	99.999998
2.10	0	0	0	5.6	0.0	73,455	2,000	146,910,000	0.0E+00	100.000000	3.8E-08	99.999996	3.8E-08	99.999996
2.57	0	0	0	5.6	0.0	183,240	2,000	366,480,000	0.0E+00	100.000000	1.5E-08	99.999998	1.5E-08	99.999998
3.46	0	0	0	5.6	0.0	89,490	2,000	178,980,000	0.0E+00	100.000000	3.1E-08	99.999997	3.1E-08	99.999997
4.47	0	0	0	5.6	0.0	37,005	2,000	74,010,000	0.0E+00	100.000000	7.6E-08	99.999992	7.6E-08	99.999992
5.24	0	0	0	5.6	0.0	12,030	2,000	24,060,000	0.0E+00	100.000000	2.3E-07	99.999977	2.3E-07	99.999977
6.20	0	0	0	5.6	0.0	15,705	2,000	31,410,000	0.0E+00	100.000000	1.8E-07	99.999982	1.8E-07	99.999982
8.37	0	0	0	5.6	0.0	6,750	2,000	13,500,000	0.0E+00	100.000000	4.2E-07	99.999958	4.2E-07	99.999958

Canister R57B  
Flowrate (lpm) 25  
Test Number 01100303

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	34	6546	6512	3.5	22929.6	2,102,760	2,000	4,205,520,000	5.5E-06	99.999455	2.8E-08	99.999997	5.5E-06	99.999455
0.45	4	507	503	3.5	1771.1	1,526,175	2,000	3,052,350,000	5.8E-07	99.999942	4.6E-09	100.000000	5.8E-07	99.999942
0.52	0	25	25	3.5	88.0	292,710	2,000	585,420,000	1.5E-07	99.999985	6.0E-09	99.999999	1.5E-07	99.999985
0.62	1	21	20	3.5	70.4	736,350	2,000	1,472,700,000	4.8E-08	99.999995	2.4E-09	100.000000	4.8E-08	99.999995
0.84	0	5	5	3.5	17.6	1,341,630	2,000	2,683,260,000	6.6E-09	99.999999	1.3E-09	100.000000	6.6E-09	99.999999
1.14	0	0	0	3.5	0.0	517,485	2,000	1,034,970,000	0.0E+00	100.000000	3.4E-09	100.000000	3.4E-09	100.000000
1.44	0	0	0	3.5	0.0	258,210	2,000	516,420,000	0.0E+00	100.000000	6.8E-09	99.999999	6.8E-09	99.999999
1.79	0	0	0	3.5	0.0	210,225	2,000	420,450,000	0.0E+00	100.000000	8.4E-09	99.999999	8.4E-09	99.999999
2.10	0	0	0	3.5	0.0	97,965	2,000	195,930,000	0.0E+00	100.000000	1.8E-08	99.999998	1.8E-08	99.999998
2.57	0	0	0	3.5	0.0	238,980	2,000	477,960,000	0.0E+00	100.000000	7.4E-09	99.999999	7.4E-09	99.999999
3.46	0	0	0	3.5	0.0	124,395	2,000	248,790,000	0.0E+00	100.000000	1.4E-08	99.999999	1.4E-08	99.999999
4.47	0	0	0	3.5	0.0	50,535	2,000	101,070,000	0.0E+00	100.000000	3.5E-08	99.999997	3.5E-08	99.999997
5.24	0	0	0	3.5	0.0	18,165	2,000	36,330,000	0.0E+00	100.000000	9.7E-08	99.999990	9.7E-08	99.999990
6.20	0	0	0	3.5	0.0	24,285	2,000	48,570,000	0.0E+00	100.000000	7.2E-08	99.999993	7.2E-08	99.999993
8.37	0	0	0	3.5	0.0	10,770	2,000	21,540,000	0.0E+00	100.000000	1.6E-07	99.999984	1.6E-07	99.999984

Canister R57B  
Flowrate (lpm) 15  
Test Number 01130301

	A	B	C	D	E	F	G	H	i	J	K	L	M	N
Particle Diameter (µm)	Background Penetration count (raw summation)	Penetration count (raw summation)	Penetration counts minus bkg counts (B - A)	Sampling ratio (canister flow / OPC flow)	Penetration counts x sampling ratio (C x D)	Challenge Count sum	Dilution factor on Challenge counts	Challenge x dilution factor (F x G)	Computed Penetration (E / H)	Computed Efficiency (%); 100 x (1 - i)	Detection limit on Penetration	Detection limit on Efficiency	Report Penetration	Report Efficiency (%)
0.35	5	1577	1572	2.1	3321.1	2,817,990	2,000	5,635,980,000	5.9E-07	99.999941	1.9E-09	100.000000	5.9E-07	99.999941
0.45	0	196	196	2.1	414.1	2,077,695	2,000	4,155,390,000	1.0E-07	99.999990	5.1E-10	100.000000	1.0E-07	99.999990
0.52	0	11	11	2.1	23.2	403,395	2,000	806,790,000	2.9E-08	99.999997	2.6E-09	100.000000	2.9E-08	99.999997
0.62	0	10	10	2.1	21.1	1,004,580	2,000	2,009,160,000	1.1E-08	99.999999	1.1E-09	100.000000	1.1E-08	99.999999
0.84	0	6	6	2.1	12.7	1,792,530	2,000	3,585,060,000	3.5E-09	100.000000	5.9E-10	100.000000	3.5E-09	100.000000
1.14	0	0	0	2.1	0.0	724,065	2,000	1,448,130,000	0.0E+00	100.000000	1.5E-09	100.000000	1.5E-09	100.000000
1.44	0	0	0	2.1	0.0	369,240	2,000	738,480,000	0.0E+00	100.000000	2.9E-09	100.000000	2.9E-09	100.000000
1.79	0	0	0	2.1	0.0	297,810	2,000	595,620,000	0.0E+00	100.000000	3.5E-09	100.000000	3.5E-09	100.000000
2.10	0	0	0	2.1	0.0	129,510	2,000	259,020,000	0.0E+00	100.000000	8.2E-09	99.999999	8.2E-09	99.999999
2.57	0	0	0	2.1	0.0	311,625	2,000	623,250,000	0.0E+00	100.000000	3.4E-09	100.000000	3.4E-09	100.000000
3.46	0	0	0	2.1	0.0	148,215	2,000	296,430,000	0.0E+00	100.000000	7.1E-09	99.999999	7.1E-09	99.999999
4.47	0	0	0	2.1	0.0	57,315	2,000	114,630,000	0.0E+00	100.000000	1.8E-08	99.999998	1.8E-08	99.999998
5.24	0	0	0	2.1	0.0	18,690	2,000	37,380,000	0.0E+00	100.000000	5.7E-08	99.999994	5.7E-08	99.999994
6.20	0	0	0	2.1	0.0	24,555	2,000	49,110,000	0.0E+00	100.000000	4.3E-08	99.999996	4.3E-08	99.999996
8.37	0	0	0	2.1	0.0	8,625	2,000	17,250,000	0.0E+00	100.000000	1.2E-07	99.999988	1.2E-07	99.999988

# **Validation of Respirator Filter Efficacy**

## **Phase I Quick Look Report**

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## Validation of Respirator Filter Efficacy Preliminary Assessment of Data/Literature

### Executive Summary

- This project addresses the following question: Do the respirator canisters used by US military personnel (specifically the C2A1, R57B-P100, and CP3N) provide sufficient protection in light of today's chemical and biological aerosol threats? Particles in the 1-5  $\mu\text{m}$  size range are of special interest because biological aerosols are often found in this range and because particles in this range are respirable.
- The C2A1 canisters are manufactured to be a minimum of 99.990% efficient for 0.3  $\mu\text{m}$  diameter particles. Likewise, non-DOD approved canisters are tested by NIOSH to be a minimum of 99.97% efficient for 0.1 – 0.3  $\mu\text{m}$  particles. These measurements are made at or near the particle diameter of maximum penetration. Larger sized particles, such as those in the 1-5  $\mu\text{m}$  range, will be filtered to a higher, **but as yet unmeasured**, degree.
- The literature has limited information on the performance of HEPA-grade filters and canisters for micron sized aerosol particles.
- The critical question is whether 99.990% efficiency (and 99.97% for non-DOD canisters) is adequate for chemical and biological aerosol challenges that may be encountered during field operations:
  - Calculations based on exposure conditions in the statement of work show that if the infectious dose for a bioaerosol agent is ~100 particles per person or less, efficiencies significantly greater than 99.99% are needed.
  - Thus, the efficiency of the canisters needs to be measured over size ranges representative of these challenges, i.e., over the 1-5  $\mu\text{m}$  size range.
  - The canisters may already provide the needed higher efficiency levels, but their actual level of efficiency has not been confirmed over this size range.
- **Therefore, if 99.97 – 99.99% is not an adequate level of protection, it is recommended that Phase II of this program be undertaken to provide direct measurement of filtration efficiency for the C2A1 and other canisters for aerosols in the 1-5  $\mu\text{m}$  range.** Phase II will challenge the canisters with 1  $\mu\text{m}$  bioaerosol (BG spores) and inert particles over a range of sizes from 0.3 – 10  $\mu\text{m}$ . Results from these tests will fill a gap in existing canister performance data. It is expected that the efficiencies will exceed 99.99%; however confirmation and quantification to higher efficiency levels is needed.

## 1.0 Introduction

The project's object is to characterize, validate and document the filtration efficiency of military gas mask canisters for use within high concentration biologically contaminated environment. The overall intent is to baseline the C2A1, R57B-P100, and CP3N filter canisters for use within biologically contaminated environments.

This project addresses the following question: Do the respirator canisters used by US military personnel provide sufficient protection in light of today's chemical and biological aerosol threats? The 1-5  $\mu\text{m}$  range is of particular interest as it encompasses the size range of many bioaerosols. The critical issues are:

- A. Is an efficiency of 99.97%, if assumed for all particle sizes, sufficient protection for anticipated field scenarios? If so, then additional testing is not likely needed. The standard tests are conducted at or near the "most penetrating particle size" and larger sized particles, such as those in the 1-5  $\mu\text{m}$  range, will be filtered to a higher, although unmeasured, degree. This is discussed in Section 2.
- B. If 99.97% is not adequate, then what efficiency is needed? If the infectious dose and/or chemical toxicity levels of aerosolized chemical and biological threats has changed, higher levels of protection may be needed. This is discussed in Section 3.
- C. If 99.97% efficiency is not adequate, then the efficiency of the canisters for particles in the 1-5  $\mu\text{m}$  range should be measured. There is very little data on HEPA filter efficiencies for this size range. A review of current literature is provided in Section 4.
- D. Do the MIL-STD and NIOSH test conditions adequately challenge the canisters and quantify their performance in light of possible military use scenarios? Breathing rates, challenge levels, chemical toxicity and infectious dose are all factors that could impact how the tests are run and to what level efficiency is quantified. Results from this program will help address this question.
- E. For non-DOD qualified canisters (the R57B-P100 and CP3N), is lower-than-expected performance possible due to leakage? What level of quality control do the manufacturers subject the non-DOD qualified canisters to? Are these canisters "lot certified" in a manner similar to that required of the C2A1? Multiple samples of each respirator canister will be tested to help evaluate this issue.

Our recommendations, rationale, and plans for conducting the Phase II testing of this program are presented in Sections 5 and 6.

## 2.0 Filtration Process and test methods

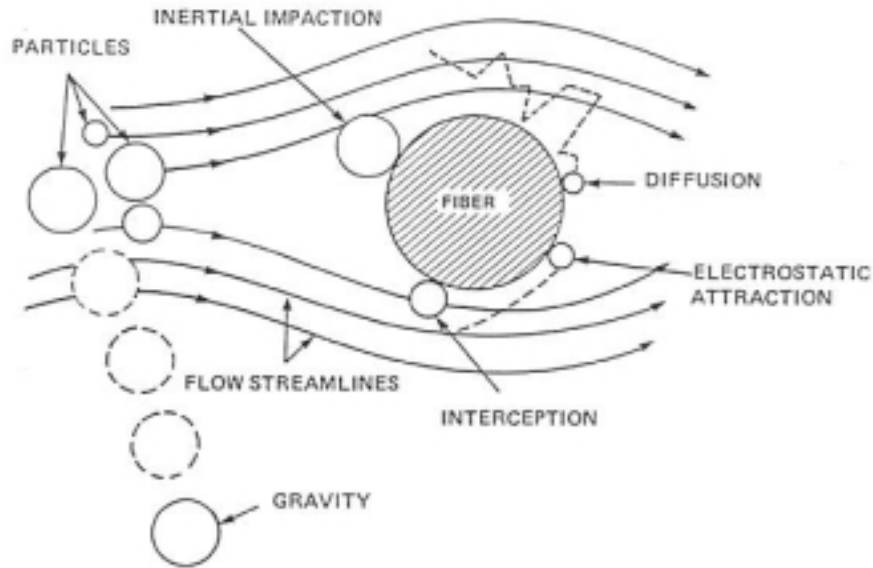
The C2A1 canisters are manufactured to be a minimum of 99.990% efficient at 0.3  $\mu\text{m}$  (MIL-PRF-5156A). Likewise, non-DOD approved canisters are tested by NIOSH test (42 CFR Part 84). Both these tests challenge the filter with particles that are near the particle size of maximum penetration (approximately 0.1 – 0.3  $\mu\text{m}$ ). Particles of other sizes (larger or smaller), such as those in the 1-5  $\mu\text{m}$  range, will be filtered to a higher degree. These tests are performed with inert test aerosol such as oil and/or salt aerosol particles.

The existence of a “most penetrating particle size” arises from the interaction of the physical mechanisms of diffusion, interception, impaction, particle bounce, and, for charged media, electrostatic attraction (Figure 1). Diffusion controls the behavior for particles less than about 0.1  $\mu\text{m}$  and becomes more dominant as particle size decreases. Diffusion is the result of the random, Brownian motion the particles undergo due to collisions with air molecules. Interception becomes important for particle sizes above about 0.1  $\mu\text{m}$ . Interception occurs when a particle comes into contact with the fiber while following the flow streamline. Impaction is important for particles greater than a few tenths of a micrometer and occurs when the particles deviate from the flow streamlines due to their inertia (Hinds, 1982). In addition to these mechanisms of particle capture, in low efficiency media, particle bounce and reentrainment can be an important factor for particles in the 3 - 10  $\mu\text{m}$  range.

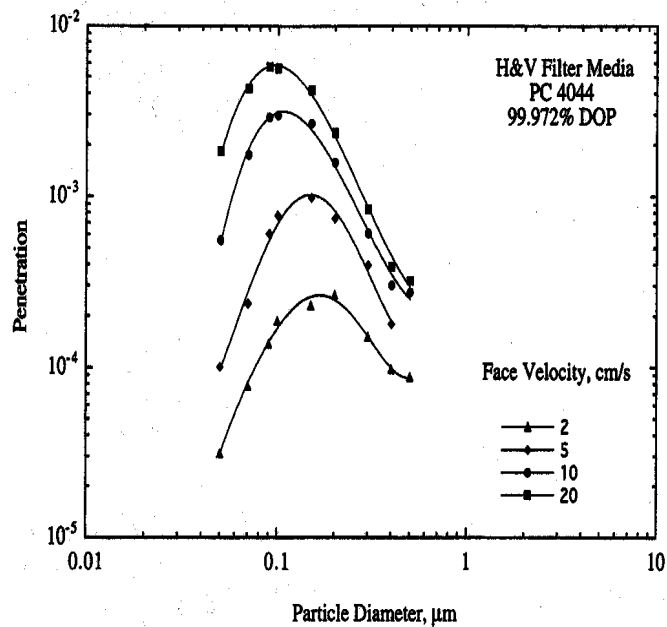
The result of the above physical filtration processes is that filtration efficiency is highly dependent upon particle size, with a minimum in efficiency typically in the 0.1 - 0.2  $\mu\text{m}$  range (Figure 2). For 1-5  $\mu\text{m}$  bioaerosol particles, collection in HEPA media will be controlled primarily by interception and impaction processes.

Figure 3 shows photographs taken under the electron microscope of HEPA media taken from a commercial respirator canister. As seen, the filter is composed of a random collection of long fibers having diameters ranging from approximately 0.3 – 3  $\mu\text{m}$ . Like all air filters, the bulk of the filter volume is open space allowing air to flow through the filter. Only the largest particles (larger than several microns for this media) will be collected on the surface by a straightforward sieving effect. The smaller particles will flow into the filter bed and will be subject to collection by diffusion, interception and impaction.

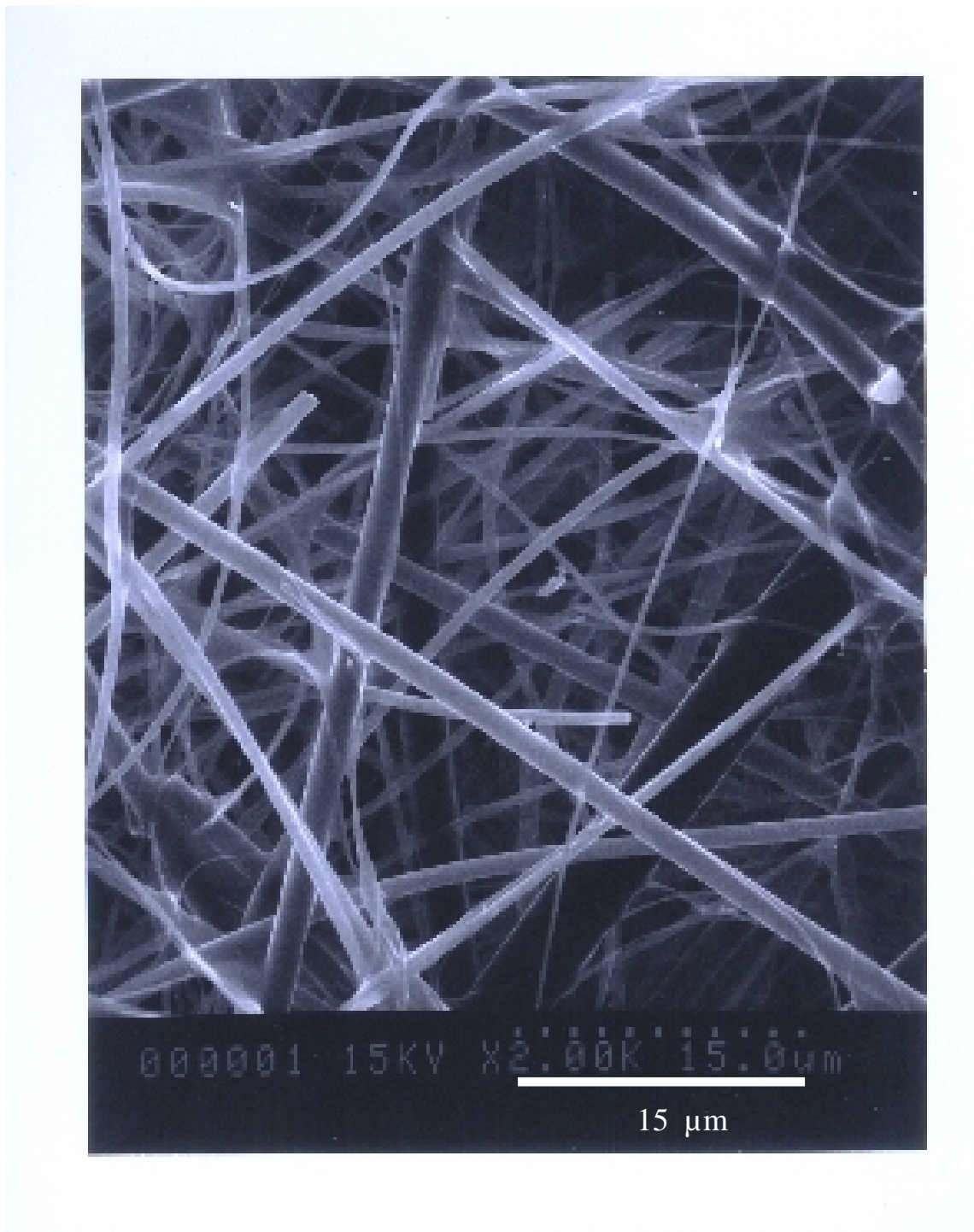




**Figure 1. Classical mechanisms of aerosol capture.**



**Figure 2. The effect of the filtration mechanisms on filter performance leads to a minimum in efficiency in the 0.1 – 0.3 μm range. Exact size of maximum penetration depends on filter properties and face velocity. This figure also illustrates the influence of face velocity on penetration. (Dhaniyala and Liu, 1999)**



**Figure 3. Photograph of the surface of a commercial HEPA respirator media under high magnification. Fiber diameter is approximately 1  $\mu\text{m}$ . Filter thickness is approximately 0.012 inches (300  $\mu\text{m}$ ), this photo is only looking at upper-most portion of the filter.**

### 3.0 Dose to Person

A 1980's unpublished ECBC report presented calculations of the required degree of filtration needed to protect a respirator wearer from a given challenge concentration and toxicity or infectious dose. We have adopted a similar approach in Sections 3.1 – 3.3.

#### 3.1 Bioaerosols

The number of contaminant bioaerosol particles inhaled by a person wearing a respirator may be express as:

$$\text{Number of particles inhaled} = C T Q (P1 + P2) \quad (\text{eqn 1})$$

Where:

**C** is the number concentration of contaminant

**T** is the exposure time in the contaminated environment

**Q** is the average inhalation breathing rate

**P1** is the penetration of the respirator filter at breathing rate Q

**P2** is penetration via mask leakage at breathing rate Q.

$P2 = 1 / FF$  where FF is mask fit factor

**Number of particles inhaled:** assumes all particles penetrating the filter canister or mask seal are inhaled and do not deposit elsewhere within the mask.

This expression is somewhat simplified in that P1 and P2 are both a function of Q, and Q is taken to be constant whereas actual breathing is naturally a cyclic process.

#### 3.2 Toxins

The mass of contaminant chemical particles inhaled by a person wearing a respirator may be express as:

$$\text{Mass of particles inhaled} = C T Q (P1 + P2) \quad (\text{eqn 2})$$

Where C is now the mass concentration of contaminant and the other parameters are as defined in eqn 1.

#### 3.3 Calculating Particle Penetration Based on Assumed Canister Efficiency Values

If an estimate of the challenge CT is known, equations (1) and (2) can be used to provide estimates of the number and mass of particles inhaled by the respirator wearer for a range of assumed canister efficiencies. These estimates can be computed over a range of breathing rates, mask fit factors. Furthermore, if the toxicity or infectious dose of the agent is known, the minimum efficiency provided by the respirator can be computed.

The statement of work leading to this project provided a range of challenge concentrations, exposure times and breathing rates. Using these values, equation 1 was used to estimate the number of inhaled particles for a range of challenge conditions. Table 1 shows the number of particles approaching the filter. Given the filter's high efficiency, this is essentially the number

**Table 1. The number of particles reaching filter for indicated conditions.**

			Number of particles reaching filter for indicated breathing rate			
<b>C</b>	<b>T</b>	<b>CT</b>	<b>Breathing rate (lpm)</b>			
<b>#/m3</b>	<b>hr</b>	<b># min / m3</b>	<b>10</b>	<b>30</b>	<b>50</b>	<b>80</b>
500	1	3.0E+04	300	900	1,500	2,400
500	2	6.0E+04	600	1,800	3,000	4,800
500	4	1.2E+05	1,200	3,600	6,000	9,600
500	8	2.4E+05	2,400	7,200	12,000	19,200
500	12	3.6E+05	3,600	10,800	18,000	28,800
5,000	1	3.0E+05	3,000	9,000	15,000	24,000
5,000	2	6.0E+05	6,000	18,000	30,000	48,000
5,000	4	1.2E+06	12,000	36,000	60,000	96,000
5,000	8	2.4E+06	24,000	72,000	120,000	192,000
5,000	12	3.6E+06	36,000	108,000	180,000	288,000
50,000	1	3.0E+06	30,000	90,000	150,000	240,000
50,000	2	6.0E+06	60,000	180,000	300,000	480,000
50,000	4	1.2E+07	120,000	360,000	600,000	960,000
50,000	8	2.4E+07	240,000	720,000	1,200,000	1,920,000
50,000	12	3.6E+07	360,000	1,080,000	1,800,000	2,880,000

**Table 2. Number of particles penetrating filter for indicated conditions and assumed canister efficiency. 4 hr exposure time shown; see Appendix A for additional conditions.**

				Number of particles penetrating filter for indicated conditions			
<b>C</b>	<b>T</b>	<b>CT</b>	<b>Canister</b>	<b>Breathing rates (lpm)</b>			
<b>#/m3</b>	<b>hr</b>	<b># min / m<sup>3</sup></b>	<b>Efficiency (%)</b>	<b>10</b>	<b>30</b>	<b>50</b>	<b>80</b>
500	4	1.2E+05	99.97	0	1	2	3
500	4	1.2E+05	99.99	0	0	1	1
500	4	1.2E+05	99.999	0	0	0	0
500	4	1.2E+05	99.9999	0	0	0	0
500	4	1.2E+05	99.99999	0	0	0	0
5,000	4	1.2E+06	99.97	4	11	18	29
5,000	4	1.2E+06	99.99	1	4	6	10
5,000	4	1.2E+06	99.999	0	0	1	1
5,000	4	1.2E+06	99.9999	0	0	0	0
5,000	4	1.2E+06	99.99999	0	0	0	0
50,000	4	1.2E+07	99.97	36	108	180	288
50,000	4	1.2E+07	99.99	12	36	60	96
50,000	4	1.2E+07	99.999	1	4	6	10
50,000	4	1.2E+07	99.9999	0	0	1	1
50,000	4	1.2E+07	99.99999	0	0	0	0

of particles that will be captured by the filter for the given C, T, and Q. The number of particles reaching the filter range from 300 to 2,880,000 for the conditions specified.

Table 2 shows how many particles would be expected to penetrate the filter for efficiencies ranging from 99.97% up to 99.99999% for the particles. As seen in Table 2, at 99.97% efficiency, significant particle penetration occurs for some conditions (288 particles penetrate for the worst-case condition). Even at 99.9999% efficiency, 1 particle penetrates at the worst-case condition. At 99.99999%, no particles would be expected to penetrate the filter canister for the conditions cited. For conciseness, Table 2 is limited to just one exposure time of 4 hours. Tables in Appendix A provide data for exposure times ranging from 1 to 12 hours.

### 3.4 Mask Fit Factor and other leak sources

In the above calculations, we have assumed P2 (penetration through the mask seal) to be zero. In reality, non-zero seal leaks may be expected, especially in negative pressure respirators. Mask seal is often expressed as fit factor computed as the ratio of the particle concentration outside the mask to the concentration of particles inside the mask. Table 3 shows the relationship of mask fit factor to “respirator efficiency” assuming the respirator filter canister had zero penetration. As shown, a fit factor of 10,000 corresponds to a respirator efficiency of 99.99%. Thus, even if the respirator canisters operated at efficiencies higher than this, a respirator worn with a fit factor of 10,000 would only be 99.99% efficient. In Table 2, that would mean using particle penetration values associated with 99.99%.

**Table 3. Mask fit factor may limit respirator performance.  
Respirator efficiency for a range of fit factors.**

<b>Fit Factor</b>	<b>Respirator efficiency</b>
100	99%
1,000	99.9%
10,000	99.99%
100,000	99.999%

## 4. Literature Search / Existing Data

### 4.1 Literature data

A literature search was conducted existing test data on the filtration efficiency of high efficiency respirator canisters. Findings thus far are summarized below, with additional detail provided in Appendix B.

- Measurements were made of the penetration of three bioaerosol and one inert aerosol through HEPA canisters, including the R57B canister of interest to this program. The canisters were tested against three bioaerosols ranging in size from 0.69 – 0.88  $\mu\text{m}$  aerodynamic diameter (Mycobacterium abscessus, staphylococcus epidermidis, and

*Bacillus subtilis*). Penetrations for the HEPA canisters were found to be approximately 0.01% - 0.02% (99.99% - 99.98% efficiency). It is unclear if these tests were performed at 45 or 85 lpm. (Brosseau et al., 1997 and McCullough et al., 1997)

- Several investigators have measured the penetration of BG spores (approximately 1  $\mu\text{m}$ ) through lower-efficiency respirators (e.g., NIOSH N95). They found that the filtration efficiency for BG was significantly higher than the rated efficiency of the canister (typically measured at 0.1 – 0.3  $\mu\text{m}$ ); however, the quantification of these measurements was limited to a maximum efficiency of from 99% to about 99.99%. (Harstad et al., 1967, Harstad and Filler, 1969, Qian et al., 1998.)
- Several studies measured penetration for both bioaerosols and inert particles (such as salt or oil). They found that for a given particle size, the degree of penetration was the same for biological and inert particles. (Chen et al, 1994, Brosseau et al., 1994, and Foarde and Hanley, 2002.)
- Several papers include faceseal leakage in their measurements or discussion when dealing with a complete respirator. Another investigated inward leakage at the exhalation valve. While the present study is limited to canister performance, full respirator studies may be warranted because mask-to-face seal and valve leakage may be what limits a respirator's efficiency to values well below those obtained by the canisters themselves. (Johnson et al., 1994, Bellin and Hinds, 1990)

The findings are insufficient for stating the filtration efficiency of HEPA canisters for bioaerosol in the 1-5  $\mu\text{m}$  range. Only the work by Brosseau et al., 1997 and McCullough et al., 1997 (part of the same investigative team) include well-quantified efficiencies for HEPA canisters on micron-sized bioaerosols. However, their measurements did not go above approximately 1 $\mu\text{m}$  and did not include the C2A1 or CP3N canisters. Their measurement of efficiencies of only ~99.99% raise some concern as higher efficiencies would have been expected. Thus, their work reinforces the need for further testing of the respirator canisters.

The issues of faceseal and exhaust valve leakage are important and should not be overlooked in estimating overall respirator protection, however, these are not the focus of this project.

#### **4.2 Numerical Models to Predict Filter Performance**

Equations for each of the filter processes (diffusion, interception, impaction as discussed in Section 2) have been presented by a number of investigators (a good summary is presented by Hinds, 1982). These combine theoretical formulations with empirical adjustments added to bring the results in line with direct experimental measurement. These investigations have been primarily concerned with filter behavior around the point of the most penetrating particle size (i.e., in the 0.005 – 0.05  $\mu\text{m}$  range). The formulations can be combined into a numerical model that can be used as a filter design tool and, with significant limitations, to predict filter performance.

As an illustration of this approach, Table 4 presents predicted filter performance based on one set of input conditions. Note, that in this case, the solidity was adjusted to yield 99.97% efficiency at 0.3  $\mu\text{m}$ ; this scales the calculations to a known reference point. It must be understood that extrapolation of these equations to 5  $\mu\text{m}$  is going well beyond the range of their supporting experimental measurements; indeed, such low penetrations are for all practical purposes impossible to verify. *We show these values simply to illustrate that such models predict extremely low penetrations in the 1-5  $\mu\text{m}$  range. These should not be mistaken for actual estimates of performance.* The values do, however, illustrate that filtration efficiency is expected to increase rapidly with particle size.

**Table 4. Numerical extrapolation (following equations presented by Hinds, 1982) of large particle filtration efficiency and penetration beginning with 99.97% @ 0.3  $\mu\text{m}$  for 10 cm/s face velocity, a fiber diameter of 0.9  $\mu\text{m}$ , a 0.07 solidity, a 0.3 mm media thickness, and a particle density of 1 g/cm<sup>3</sup>). For illustrative purposes only.**

<b>Diameter (<math>\mu\text{m}</math>)</b>	<b>0.3</b>	<b>0.5</b>	<b>0.7</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>5</b>
<b>Efficiency (%)</b>	99.97	99.9999993	-	-	-	-	-
<b>Penetration (%)</b>	$3 \times 10^{-2}$	$3 \times 10^{-7}$	$\sim 10^{-13}$	$\sim 10^{-24}$	$\sim 10^{-40}$	$\sim 10^{-55}$	$\sim 10^{-83}$

It is very important to note, however, that if the filter contains pin-hole leaks through the media, or leaks between the media and canister shell, or leaks in the seams of the canister shell itself, the penetration curve would be expected to be much more constant across particle size. The “filtration” provided when leaks are present is simply due to dilution of the leak flow with the filtered flow; the aerosol particles flowing through the leak are not filtered, although some may still be collected by impaction with various surfaces along the flow path.

These models also do not account for non-ideal effects such as particle reentrainment, vibrations, tidal flow, etc. It is not known if these non-ideal conditions would significantly reduce the canister’s efficiency.

## **5. Recommended Phase II Approach**

### **5.1 Test Conditions and Overall Strategy**

Phase II will provide direct measurement of canister filtration efficiency for particles in the 1-5  $\mu\text{m}$  range. Flow rates through the canisters will range from 10 to 80 lpm. Three types of canisters will be tested: C2A1, R57B-P100 and the CP3N. The test matrix is presented in Table 5. The degree of replication will depend the test durations that are as yet undetermined.

The canisters will be challenged with both bioaerosol and inert aerosols. The bioaerosol will be BG spores that are approximately 1  $\mu\text{m}$  in size. The inert tests will be performed to overlap the BG test results and to extend the efficiency to a wider range of particle sizes (0.3 – 10  $\mu\text{m}$ ). Also, one of these two approaches may allow quantification to higher efficiency levels than the other; it is not presently know if that will be the bioaerosol or inert aerosol approach.

Based on a review of NIOSH and DOD test practices, the canisters will be challenged in an “encapsulated” testing mode. This involves exposing the entire exterior surface of the canister to the challenge aerosol. This is done so that the test is able to detect any inward leakage at seams of the canister.

We do not expect the canister efficiency to be dependent upon challenge concentration. However, our ability to measure penetration is strongly tied to the challenge level; the greater the challenge level, the greater we can state the minimum efficiency to be. Therefore, we plan to expose the canisters to a high concentration aerosol challenge environment that will be held approximately the same for each bioaerosol, and for each inert aerosol, test.

It should be noted that in many cases we might detect no particles downstream of the canister. In that event, the degree of efficiency will be based on the number of upstream particle counts and count statistics. Such values would be reported as, for example, >99.99%, or > 99.999%, or >99.9999%, etc depending primarily upon the magnitude of the challenge particle counts presented to the intake of the canister. The challenge level will be dependent upon the respirator flow rate.



**Table 5. Test Series. Testing will be performed at four flowrates, for three canisters with BG and inert aerosols. The degree of replication will be determined after test durations are known.**

<b>Flow Rate (lpm)</b>	<b>Challenge Aerosol</b>	<b>Canister</b>
10	BG spores	C2A1
30	BG spores	C2A1
50	BG spores	C2A1
80	BG spores	C2A1
10	BG spores	R57B-P100
30	BG spores	R57B-P100
50	BG spores	R57B-P100
80	BG spores	R57B-P100
10	BG spores	CP3N
30	BG spores	CP3N
50	BG spores	CP3N
80	BG spores	CP3N
10	Salt 0.3 – 10 µm	C2A1
30	Salt 0.3 – 10 µm	C2A1
50	Salt 0.3 – 10 µm	C2A1
80	Salt 0.3 – 10 µm	C2A1
10	Salt 0.3 – 10 µm	R57B-P100
30	Salt 0.3 – 10 µm	R57B-P100
50	Salt 0.3 – 10 µm	R57B-P100
80	Salt 0.3 – 10 µm	R57B-P100
10	Salt 0.3 – 10 µm	CP3N
30	Salt 0.3 – 10 µm	CP3N
50	Salt 0.3 – 10 µm	CP3N
80	Salt 0.3 – 10 µm	CP3N

## 5.2 Bioaerosol Test Strategy

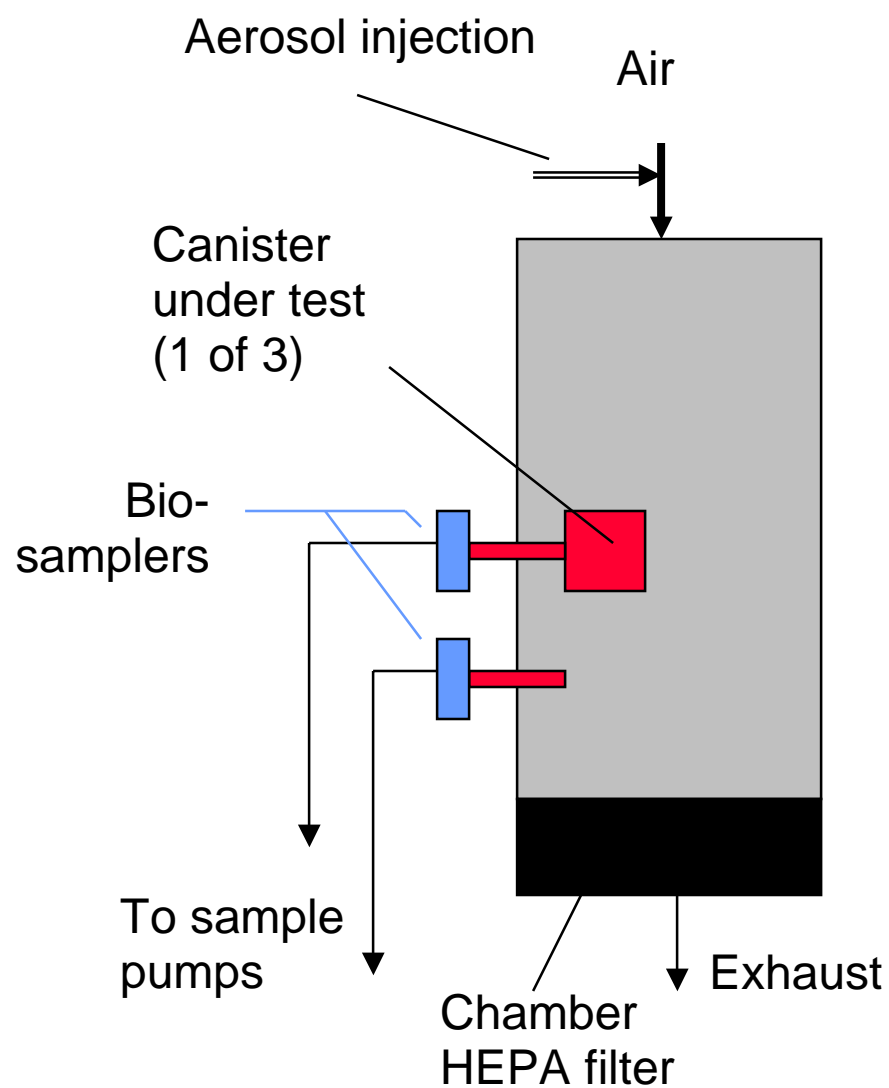
The bioaerosol tests will be conducted using the spore form of the microorganism *Bacillus atrophaeus* (formerly *Bacillus globigii* or BG). The BG spore is elliptically shaped with dimensions of ~0.7 - 0.8 X 1 - 1.5µm. The BG spores will be aerosolized from aqueous suspension using a 24-jet Collison nebulizer. The output of the nebulizer will be dried and charge-neutralized prior to introduction to the exposure chamber. The objective of the generation system is to produce a stable high concentration aerosol of individual BG spores. A 6-stage bioaerosol impactor will be used during pretests to confirm that the spores are being generated as single spores as opposed to multi-spore clusters.

The exposure chamber, illustrated in Figure 4, is an acrylic chamber with a working volume of 24" x 24" x 48". The chamber had been used in prior RTI bioaerosol studies and is well suited to the requirements of this project. The aerosol will be introduced at the top at a flowrate of 10 cfm. A rotating baffle ensures well-mixed conditions within the chamber.

It is planned that each run will test will test three canisters and one chamber monitor operated simultaneously. The canisters will be operated at one of the test flows (10 – 80 lpm). The chamber monitor will either be operated at a fixed rate of for all tests or will vary with the canister flow; preliminary testing will determine the best approach.

We anticipate that the bioaerosol will be sampled using 37mm 0.45 µm pore membrane filters in prepackaged, sterile, disposable air monitoring cassettes. A cassette will be mounted directly downstream of the respirator canister. The entire sample flow will flow through the cassette filter; i.e., the biosampler samples 100% of the canister flow. The use of the prepackaged, sterile cassettes minimizes contamination opportunities. Using membrane filters, as opposed to depth filters, facilitates complete suspension of collected spores. At the higher sample flows, we may not be able to sample 100% of the flow; if this occurs, isokinetic sub-sampling will be performed. The final selection of filter size, pore diameter, and sample configuration will be determined during preliminary testing.

Depending upon the anticipated spore concentration on the membrane collection filter, one of three approaches will be applied to quantify the number of spores. To quantify the chamber bioaerosol challenge concentration, the chamber monitor filter will be placed in a sterile receptacle containing phosphate-buffered saline with 0.1% Tween 80 and agitated to suspend the collected BG spores. Dilutions of the suspension will be made as needed. Approximately 1% of this suspension will be diluted and replicates plated on tryptic soy agar. The plates will be incubated at 32°C overnight. Colony forming units (CFUs) will be counted shortly after mature growth is noted. The spore concentrations on the filters downstream of the canisters are anticipated to be many times lower than the chamber concentration. As discussed earlier, some filters may have 0 spores. The key issue will be to lower the minimum detection limit. Rather than suspending the membrane filter in buffer and plating an aliquot of the suspension, we plan to place the filter directly on the surface of the tryptic soy agar plate. In theory, the agar will diffuse through the membrane filter and the organisms will grow directly on the filter. Another approach is to elute the spores from the surface of the membrane filter and filter all the eluate through a more porous filter. This filter will then be placed directly on the surface of the tryptic



**Figure 4. Schematic diagram of bioaerosol test chamber.**

soy agar plate and enumerated. The final approach will be determined during preliminary testing.

Control tests for background level quantification, expected to be zero, will be performed.

### 5.3 Inert Particle Test Strategy

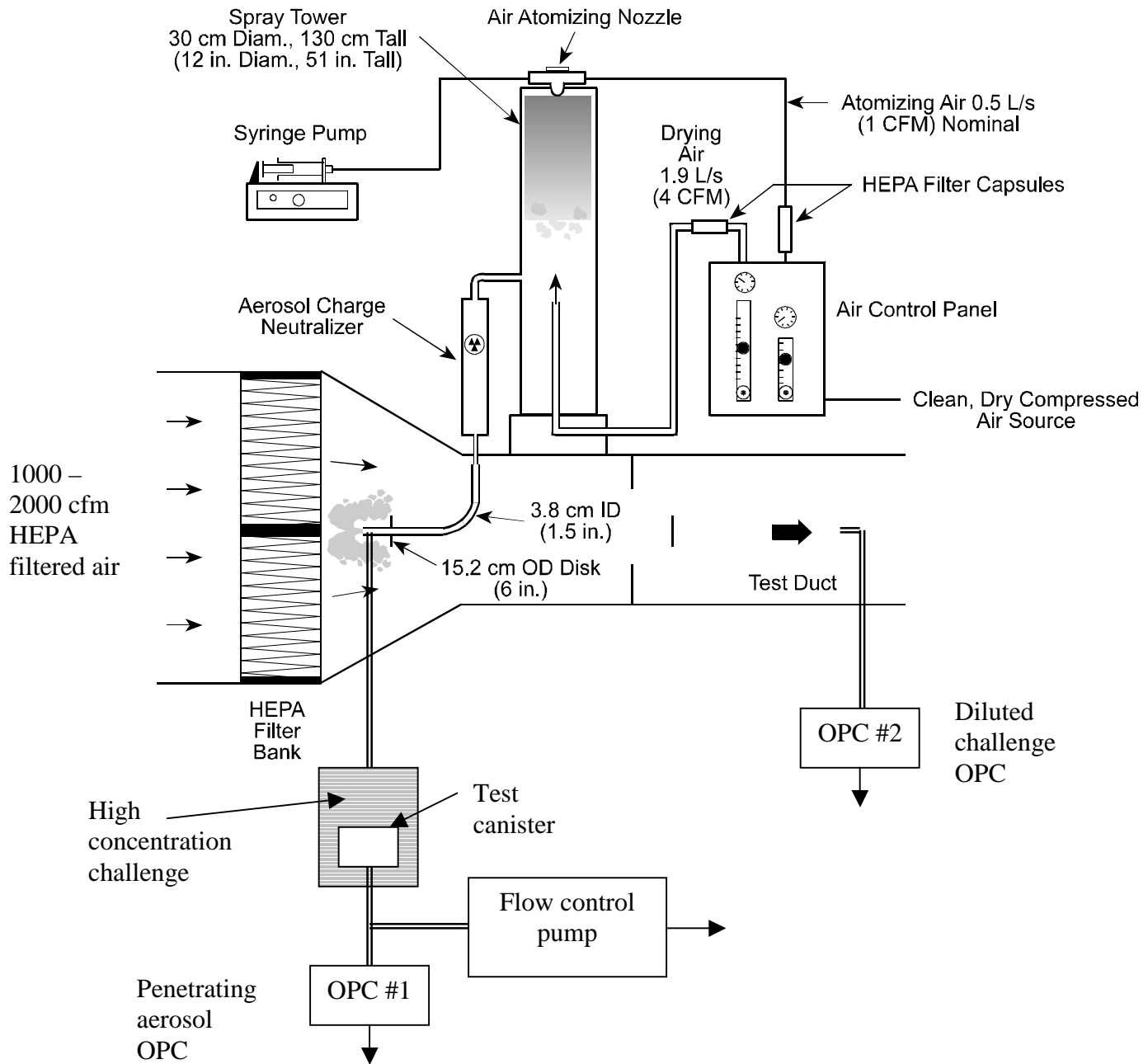
Inert particle testing will be performed to expand the size range covered by the bioaerosol measurements. The inert challenge will be a polydisperse aerosol of dried, charge-neutral potassium chloride salt aerosol covering the range from 0.3 – 10  $\mu\text{m}$ . Aerosol concentrations upstream and downstream of the respirator will be measured with a pair of aerosol particle counters (Climet CI-500 or similar). The aerosol counters simultaneously count and size airborne particles in real time by drawing a continuous air sample through a detection chamber. Each particle is individually counted and sized (at rates up to thousands per second). From these readings, the filtration efficiency of the canister will be determined for 12 particle size ranges between 0.3 and 10  $\mu\text{m}$  (Table 6).

**Table 6. Particle sizing channels of the OPC planned for the inert particle tests.**

Channel No.	Size range ( $\mu\text{m}$ )	Channel No.	Size range ( $\mu\text{m}$ )
1	0.3 – 0.4	7	1.6 – 2.2
2	0.4 – 0.55	8	2.2 – 3
3	0.55 – 0.7	9	3 – 4
4	0.7 – 1	10	4 – 5.5
5	1 – 1.3	11	5.5 – 7
6	1.3 – 1.6	12	7 – 10

These tests will likely make use of RTI's filter testing rig (Figure 5). The rig is designed for testing HVAC filters over the 0.3 – 10  $\mu\text{m}$  size range (ASHRAE test 52.2) with the KCl aerosol. We are considering two approaches. For the first, the canister will be secured directly onto the inlet of the downstream probe. Provisions will be added to vary the canister flow rate from 10 to 80 lpm. An inline dilutor will be added to the upstream OPC to provide approximately 50:1 dilution of the sample. For a higher concentration challenge, the canister may be positioned to sample directly from the high concentration spray tower (this is the set up illustrated in Figure 5). A side stream of this flow would be directed into the test duct to provide approximately 1000:1 dilution. Preliminary testing will determine which approach will be adopted for the testing.

Control tests will be performed to quantify background count levels and to quantify the achieved dilution ratio.



**Figure 5. Adaptation of 0.3-10 µm ASHRAE duct for respirator testing under consideration for Phase II testing.**

## 6. Conclusions and Recommendation

### Conclusions:

- The Phase I review found very limited information on the filtration efficiency of HEPA-grade respirator canisters for particles in the 1-5  $\mu\text{m}$  size range.
- Few studies have quantified bioaerosol efficiencies to values greater than 99% and fewer still investigated efficiencies for particle sizes above a micron.
- Calculations based on challenge concentrations, exposure times and breathing rates provided in the statement of work indicate that efficiencies well above 99.99% may be needed to protect against extremely potent chemical or biological agents.
- The C2A1, R57B-P100 and CP3N canisters have not been tested to these levels nor at these size ranges.

### Recommendations:

- We recommend that Phase II testing be initiated.
- Phase II will directly measure the filtration efficiency for the C2A1 and other canisters for aerosols in the 1-5  $\mu\text{m}$  range.
- The canisters will be challenged with a 1  $\mu\text{m}$  bioaerosol (BG spores) and inert particles over a range of sizes from 0.3 – 10  $\mu\text{m}$ .
- These results will fill a gap in existing canister performance data.
- It is expected that the efficiencies will exceed 99.99%; however confirmation and quantification of the higher efficiency levels are needed.

## 7. References

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## APPENDIX A

**Computed particle penetrations for given concentration, time, breathing rate and assumed canister filtration efficiency.**

**Table A-1. Particle penetration of filter canister for an efficiency of 99.97% (penetration = 0.03%) for the indicated concentration, time and breathing rate.**

**For canister efficiency = 99.97%**

C	T	CT	Number of particles penetrating filter for indicated breathing rate and filtration efficiency			
			Breathing rate (lpm)			
#/m3	hr	# min / m3	10	30	50	80
500	1	3.0E+04	0	0	0	1
500	2	6.0E+04	0	1	1	1
500	4	1.2E+05	0	1	2	3
500	8	2.4E+05	1	2	4	6
500	12	3.6E+05	1	3	5	9
5,000	1	3.0E+05	1	3	4	7
5,000	2	6.0E+05	2	5	9	14
5,000	4	1.2E+06	4	11	18	29
5,000	8	2.4E+06	7	22	36	58
5,000	12	3.6E+06	11	32	54	86
50,000	1	3.0E+06	9	27	45	72
50,000	2	6.0E+06	18	54	90	144
50,000	4	1.2E+07	36	108	180	288
50,000	8	2.4E+07	72	216	360	576
50,000	12	3.6E+07	108	324	540	864



**Table A-2. Particle penetration of filter canister for an efficiency of 99.99% (penetration = 0.01%) for the indicated concentration, time and breathing rate.**

**For canister efficiency = 99.99%**

C	T	CT	Number of particles penetrating filter for indicated breathing rate and filtration efficiency			
			Breathing rate (lpm)			
#/m3	hr	# min / m3	10	30	50	80
500	1	3.0E+04	0	0	0	0
500	2	6.0E+04	0	0	0	0
500	4	1.2E+05	0	0	1	1
500	8	2.4E+05	0	1	1	2
500	12	3.6E+05	0	1	2	3
5,000	1	3.0E+05	0	1	2	2
5,000	2	6.0E+05	1	2	3	5
5,000	4	1.2E+06	1	4	6	10
5,000	8	2.4E+06	2	7	12	19
5,000	12	3.6E+06	4	11	18	29
50,000	1	3.0E+06	3	9	15	24
50,000	2	6.0E+06	6	18	30	48
50,000	4	1.2E+07	12	36	60	96
50,000	8	2.4E+07	24	72	120	192
50,000	12	3.6E+07	36	108	180	288

**Table A-3. Particle penetration of filter canister for an efficiency of 99.999% (penetration = 0.001%) for the indicated concentration, time and breathing rate.**

**For canister efficiency = 99.999%**

C	T	CT	Number of particles penetrating filter for indicated breathing rate and filtration efficiency			
			Breathing rate (lpm)			
#/m3	hr	# min / m3	10	30	50	80
500	1	3.0E+04	0	0	0	0
500	2	6.0E+04	0	0	0	0
500	4	1.2E+05	0	0	0	0
500	8	2.4E+05	0	0	0	0
500	12	3.6E+05	0	0	0	0
5,000	1	3.0E+05	0	0	0	0
5,000	2	6.0E+05	0	0	0	0
5,000	4	1.2E+06	0	0	1	1
5,000	8	2.4E+06	0	1	1	2
5,000	12	3.6E+06	0	1	2	3
50,000	1	3.0E+06	0	1	2	2
50,000	2	6.0E+06	1	2	3	5
50,000	4	1.2E+07	1	4	6	10
50,000	8	2.4E+07	2	7	12	19
50,000	12	3.6E+07	4	11	18	29

**Table A-4. Particle penetration of filter canister for an efficiency of 99.9999% (penetration = 0.0001%) for the indicated concentration, time and breathing rate.**

**For canister efficiency = 99.9999%**

C	T	CT	Number of particles penetrating filter for indicated breathing rate and filtration efficiency			
			Breathing rate (lpm)			
#/m3	hr	# min / m3	10	30	50	80
500	1	3.0E+04	0	0	0	0
500	2	6.0E+04	0	0	0	0
500	4	1.2E+05	0	0	0	0
500	8	2.4E+05	0	0	0	0
500	12	3.6E+05	0	0	0	0
5,000	1	3.0E+05	0	0	0	0
5,000	2	6.0E+05	0	0	0	0
5,000	4	1.2E+06	0	0	0	0
5,000	8	2.4E+06	0	0	0	0
5,000	12	3.6E+06	0	0	0	0
50,000	1	3.0E+06	0	0	0	0
50,000	2	6.0E+06	0	0	0	0
50,000	4	1.2E+07	0	0	1	1
50,000	8	2.4E+07	0	1	1	2
50,000	12	3.6E+07	0	1	2	3

**Table A-5. Particle penetration of filter canister for an efficiency of 99.99999% (penetration = 0.00001%) for the indicated concentration, time and breathing rate.**

**For canister efficiency = 99.99999%**

C	T	CT	Number of particles penetrating filter for indicated breathing rate and filtration efficiency			
			Breathing rate (lpm)			
#/m3	hr	# min / m3	10	30	50	80
500	1	3.0E+04	0	0	0	0
500	2	6.0E+04	0	0	0	0
500	4	1.2E+05	0	0	0	0
500	8	2.4E+05	0	0	0	0
500	12	3.6E+05	0	0	0	0
5,000	1	3.0E+05	0	0	0	0
5,000	2	6.0E+05	0	0	0	0
5,000	4	1.2E+06	0	0	0	0
5,000	8	2.4E+06	0	0	0	0
5,000	12	3.6E+06	0	0	0	0
50,000	1	3.0E+06	0	0	0	0
50,000	2	6.0E+06	0	0	0	0
50,000	4	1.2E+07	0	0	0	0
50,000	8	2.4E+07	0	0	0	0
50,000	12	3.6E+07	0	0	0	0

## APPENDIX B

### Summary of applicable literature

Bellin and Hinds, 1990 investigated the degree of leakage through respirator exhalation valves. They evaluated dual cartridge half mask industrial respirators used in spray pointing operations. They found leakage into the masks of less than 0.01%. They cite an earlier study by Burgess that found penetration ranged from 0.002% to 0.05% at a work rate of 830 kg-m/min. They also cite two reports from Los Alamos National Laboratory that found inward leakage of exhaust valve was greatest at the start of the inhalation cycle and had an average leak rate of 6 ml/min during inhalation. These rates would correspond to penetrations of 0.008% and 0.02% assuming a breathing pattern associated with 622 kg-m/min work rate. (We are currently retrieving the Burgess and Los Alamos papers/reports.)

Brosseau et al, 1997 and McCullough et al, 1997, measured the penetration of three bioaerosol and one inert aerosol through a large number of low and high efficiency respirators, HEPA canisters (including the R57B canister of interest to this program) and PAPRs. Tests with 0.55  $\mu$ m PSL were able to quantify efficiencies up to 99.99999%. They found that the HEPA canisters ranged from 99.94% to 99.99996% for 0.55  $\mu$ m PSL. Several of the filters were also tested against 3 bioaerosols: *Mycobacterium abscessus* (length 1-4  $\mu$ m, width 0.3 – 0.5  $\mu$ m), *staphylococcus epidermidis* 0.5-1.5  $\mu$ m diameter), and *Bacillus subtilis* (length 2-3  $\mu$ m, width 0.5 - 0.8  $\mu$ m). The measured aerodynamic diameters of the bioaerosols were 0.69, 0.87 and 0.88, respectively. Penetrations for the HEPA canisters were found to be approximately 0.01% - 0.02% (99.99% - 99.98% efficiency) based on measurements with an aerodynamic particle sizer.

Brosseau et al, 1994, used monodisperse 0.804 polystyrene latex (PSL) and *Mycobacterium chelonae* (0.66 – 2.2  $\mu$ m aerodynamic diameter). Both yielded similar efficiency demonstrating that inert particles can be used to predict bioaerosol particle efficiency. Both these aerosols were found to penetrate to a lower degree (about 1/10<sup>th</sup>) than 0.12 polydisperse DOP.

Chen et al, 1994 tested disposable hospital surgical masks using *M. chelonae* bacterial aerosols (rod shaped 0.5 x 2  $\mu$ m) and inert latex spheres of 0.804  $\mu$ m. They found the efficiency of the HEPA mask was >99.99% (the upper limit of their experimental set up) for both challenges.

Chen 1992 tested filtering facepieces and respirator masks with attached canister against a corn oil aerosol. Results are shown for HEPA masks for particles up to 1  $\mu$ m. For a lower efficiency dust/mist mask, results are shown up to 15  $\mu$ m. The dust/mist mask had a rated efficiency of 99% for silica aerosol 0.4 - 0.6  $\mu$ m. They did not quantify for efficiencies > 99%.

Furuhashi, 1978 looked at penetration of hospital HEPA air filters in air conditioning systems when challenged with *Serratia marcescens* aerosol having a particle size of approximately 1.8 – 4.3  $\mu$ m. He reported 100% efficiency for the HEPA filters. (Note that his experimental upper limit appears to be 99.999%, so “100%” should more precisely be stated as “>99.999%”).

Harstad et al (1967) measured the penetration of bioaerosol through several commercial air filters. He found that the penetration of 1  $\mu$ m BG spores ranged from 0.000061% to 0.0028%

depending on the type of HEPA filter (the test filters were general purpose box filters designed to operate from 22 – 35 cfm). All the filters used in tests with microorganisms passed the DOP test.

Harstad and Filler (1969) measured the penetration of HEPA filters by 0.12  $\mu\text{m}$  T1 phage and 1  $\mu\text{m}$  *Bacillus subtilis* (BG) aerosols. They performed tests on both the flat-sheet filter paper and on complete highly-pleated filter units. They found that the penetration of the filter units was higher than for the flat sheet media due to internal leaks at the filter media-to-frame seal and imperfections associated with the pleating of the paper. Overall, they found that for the filter units, T1 phage penetrated at approximately  $1 \times 10^{-3} \%$  and that BG spore penetration was lower at  $5 \times 10^{-5} \%$ .

Johnson et al, 1994 tested powered air-purifying respirators (PAPR) and several disposable respirators including a surgical mask, a dust/mist respirator and a high-efficiency foam-fitting respirator. The masks were tested on a headform and they examined face seal leakage vs. direct filter penetration. Testing was performed using BG spores (*Bacillus subtilis*, rod shaped, 0.7-0.8 width and 1.5-1.8  $\mu\text{m}$  length). The PAPR units were found to be 99.95% effective against 0.8  $\mu\text{m}$  BG spores.

Qian et al, 1998 tested NIOSH type N95 respirators (95% for aerosols from 0.1 - 0.3  $\mu\text{m}$ ) with two micron-sized bioaerosols (*B. subtilis* and *B. megatherium*) and inert salt particles. Filtration efficiency measurements were performed with aerodynamic and optical particle counters. They found that efficiency increased for particles above the most penetrating size (0.1 - 0.3  $\mu\text{m}$ ) with the two bioaerosols being collected at >99.5% efficiency (99.5% was the experimental limit of their measurements).

Stafford et al, 1973 evaluated the effect of cyclic vs. steady flow conditions on respirator efficiency measurements. They used monodisperse PSL in sizes from 0.176 – 2.20  $\mu\text{m}$  and also used a 0.3  $\mu\text{m}$  DOP aerosol. They used low efficiency filters to facilitate ease of downstream detection (98.5% and 87.5% efficiencies at 0.3  $\mu\text{m}$  DOP). They found that tests under cyclic flow had significantly greater penetrations for particles below 0.3  $\mu\text{m}$  (about 10-20 times greater) and above 1.2  $\mu\text{m}$  (about 10 times greater). [Note, however, that the increased penetration above 1.2  $\mu\text{m}$  may be a result of the low efficiency filters they selected for their study; this may not be expected in HEPA grade filter media.] When comparing different degrees of cycling (i.e., different work rates), they found no definitive differences in aerosol penetration a function of cyclic-flow work rate.